TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No. 027698.001

In Re Application Of: Yoshikazu Tobinaga et al.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/666,581	September 18, 2003	Aamer S. Ahmed	21878	3763	9168

Invention: **APPLICATOR FOR APPLYING FUNCTIONAL SUBSTANCES INTO HUMAN SKIN**

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

March 31, 2006

☒ Applicant claims small entity status. See 37 CFR 1.27

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of:

Serial No.: 10/666,581)
Yoshikazu Tobinaga et al.)
Filed: September 18, 2003)
Group Art Unit: 3763)
Examiner: Aamer S. Ahmed)
For: APPLICATOR FOR APPLYING)
FUNCTIONAL SUBSTANCES INTO)
HUMAN SKIN)
)
Docket No. 027698.001)
Customer No. 21878)

Charlotte, North Carolina May 23, 2006

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APPEAL BRIEF

I. Real Parties in Interest.

The Real Parties in Interest with regard to the present application are Texmac, Inc. and Nano Device and System Research, Inc.

II. Related Appeals and Interference.

The appellants are not aware of any appeals or interference proceedings related to the present application.

III. Status of Claims.

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Claims 1-10 and 12-35 are pending in the present application.

The claims were rejected in the final Office Action of November 2, 2005, and confirmed in the Advisory Action of March 23, 2006.

The final Office Action initially states, without explanation, that Claims 1-5, 7-10, 14-16, 10-30, and 33-35 are rejected as unpatentable over Park, et al. (Pub. No. US 2002/0082543 A1) in view of D'Ussel (Pub. No. US 20040010237 A1). The final Office Action states reasons for this rejection only for Claims 1-10, 14-16, 19-32, and 34. Claim 6 was rejected on the Park prior art. Claim 11 had previously been cancelled. Claims 12, 13, and 32 were rejected on Park in view of Arias, et al. (US 20020133129 A1). Claims 17 and 18 were rejected on Park in view of Sherman, et al. (U.S. Patent No. 6,821,281). No explanation was given for the rejection of Claims 33 and 35.

IV. Status of Amendments.

The Amendment after Final Rejection of February 29, 2006, is the last Amendment entered. The form of the claims appearing in the Amendment after Final Rejection is reproduced in the attached Claims With Entered Amendments.

V. The Summary of Claimed Subject Matter.

In the following Summary, the numerals in brackets are the paragraphs numbers of the specification of the present application as filed that are referred to by the text preceding the bracketed numbers. The numerals that appear in the following text without brackets referred to the numerals appearing in the drawings of the present application. A copy of the drawings is attached hereto.

The present invention relates to the use of microneedle applicators for applying functional substances into human skin and the method of producing microneedles for this purpose. [0001]

Presently, modifying the appearance of or treating the human skin with liquid substances or powders has normally been accomplished by topographical application to the surface of the skin. For example, prior applications have been used to attempt to eliminate cornified portions of the skin in both chemical and nutritional ways, but cornification is a complicated biological phenomenon as well as being a problem, primarily occurring in the aging process. With the known types of application the substance is only temporarily retained as such substances are readily removed by perspiration, washing, unintentional contact with foreign materials and various weather conditions, making it necessary to reapply the substances on a daily or more frequent, basis. Further, any desired depth of penetration into the skin has been difficult to accurately control. Thus, there are major problems in the convenience, effectiveness, and effort in conventional applications. [0002]

Also, needles are commonly used to inject drugs, such as insulin, interferon, and pain killers, into the skin or flesh of patients, but these conventionally penetrate considerably deeper than necessary and cannot be controlled reliably as to the depth of penetration. Furthermore, they often cause pain to the patient. [0003]

Thus, there are major problems in convenience, effectiveness and effort in applying functional substances using these known types of application. [0004]

The purpose of the present invention is to apply functional substances into the human skin, particularly into the stratum corneum to enhance the appearance of the skin, to provide

cosmetic effects or chemically improve the skin or into the dermis to apply drugs to the body. By the present invention, it is possible to conveniently, safely and effectively modify or provide a desired functional effect to the surface of the skin or to apply drugs into the body using microneedles that penetrate to a controlled depth, and, do not create any undesirable sensation or pain in application. In addition, the present invention provides an effective method of producing microneedles for use in the aforesaid application. [0005]

Basically, the applicator of the present invention includes a base with a plurality of microneedles fixed to the base and projecting therefrom a distance sufficient to penetrate into the skin. The microneedles are made of a material that is capable of disintegration and dispersion into the skin when the microneedles are inserted into the skin. A functional substance is carried by the microneedles for delivery by the microneedles into the skin. The functional substance may be distributed in the material of the microneedles, such as being homogeneously distributed throughout the microneedle material, or the functional substance may be retained in recesses in the microneedles or retained in capsules that are retained in the microneedles. Preferably, the microneedles project from the base approximately 0.5 to 500μm in applying functional substances to the stratum corneum or project approximately 500 to 5,000μm in applying functional substances to the dermis. The microneedles may be cone-shaped, rectangular, square or at least partially elliptical in cross-section or any other desired shape. Preferably, the shortest side or cross-sectional dimension at the base of the microneedles is approximately 0.1 to 100μm. [0006]

Also, preferably, the microneedles are formed to facilitate breaking off at least the outer portions in the skin when the base is removed. This can be facilitated by the microneedles

having restrictions intermediate their ends or having a step between thick inner portions and thin outer portions or having barbed tips. [0007]

To facilitate insertion of the microneedles, the tips may be knife-shaped. [0008]

In one form of the invention, microcontainers containing functional substances are contained within the microneedles, preferably in recesses or within barbed tips of the microneedles. In another form, the microneedles are formed with capillary recesses in the outer portions thereof for retaining the functional substances for delivery into the skin. [0009]

The method of producing microneedles according to the present invention includes forming a microneedle pattern by x-ray lithography that irradiates an x-ray sensitive photopolymer using synchrotron x-ray radiation, then forming a mold in the reverse form of the microneedle pattern by electrotype processing. Then injection molding or casting the microneedles in the mold. [0010]

In the preferred embodiment, the material of the microneedles is a sugar that readily disintegrates upon insertion of the microneedles into the skin. Other suitable materials may be used that disintegrate into the skin upon insertion of the microneedles into the skin. [0011]

In the preferred embodiment, the x-ray sensitive photopolymer is a polymer containing polymethyl methacrylate. [0012]

In one form of the method, a functional substance is distributed, preferably homogeneously, in the material of the microneedles prior to molding. [0013]

A preferred embodiment of the applicator of the present invention is illustrated in Fig. 1. As illustrated, it is made up of a mass 12 of a plurality of microneedles attached to and

projecting from a base 13. The mass 12 contains thousands of individual microneedles that are not discernible to the naked eye. For illustrative purposes, the applicator 10 is illustrated in Fig. 1 in greatly enlarged proportion and with microneedles 14 in the mass 12 being illustrated in greatly reduced number for clarity of illustration. [0031]

As used herein, a microneedle is a needle having a length dimension in the micron range. [0032]

In the preferred embodiment, the microneedles 14 are fixed to the base 13 and project therefrom a distance sufficient to penetrate into the skin when the applicator 10 is pressed against the skin of a human. This projecting distance, when applying a functional substance into the stratum corneum, is preferably in the range of approximately 0.5 to 500μm. When the applicator is used to apply functional substances into the dermis, the projecting distance or height of the microneedles is preferably in the range of approximately 500 to 5,000μm. [0033]

The microneedles 14 are made from a suitable material that is capable of disintegration and dispersion into the stratum corneum or dermis upon insertion of the microneedles 14 into the skin. A preferred material is sugar, such as a material that is primarily 97% maltose and 3% dextran. For ease of manufacture, the microneedles 14 and the base 13 are formed integrally of the same material. Other materials may be mixed with the primary material to provide modified characteristics, such as slower release. For example, poly lactic acid may be added to slow the rate of dispersion. Materials other than sugar may be used in place of sugar that are capable of disintegrating and dispersing into the stratum corneum or dermis. For example, poly lactic acid could be used instead of sugar. [0034]

The purpose of the applicator is to apply functional substances to the stratum corneum or the dermis. For cosmetic purposes, the functional substance is preferably applied to the stratum corneum and may be a cosmetic powder, such as barium sulfate colored to a desired skin coloring, or a red food coloring substance to use as a marking, or India ink for creating a cosmetic affect, or an organic ultraviolet shield material to protect the underlying portion of the skin against ultraviolet sun rays. As the functional substance is applied into the stratum corneum, it will not readily dissipate and can provide a cosmetic effect lasting for a prolonged period of time, from a few days up to several months. [0035]

For drug applications, the drugs, such as insulin, interferon, pain killers, or any other appropriate drug, may be applied into the dermis. In the dermis, there is more moisture and it is warmer than the stratum corneum. Therefore, a drug will advantageously dissipate more quickly in the dermis than in the stratum corneum. [0036]

The functional substance 15 is carried by the microneedles 14. This may be accomplished by mixing the functional substance 15 with the main material for producing the microneedles 14 prior to forming the material into the microneedles 14. This will produce a homogeneous mix of the functional substance in the material of the microneedles 14. [0037]

With the functional substance 15 distributed in the material of the microneedles 14, the functional substance 15 will be released into the stratum corneum or dermis upon disintegration of the material of the microneedles 14 when the applicator 10 is applied to the skin of a human. A typical microneedle 15 is illustrated in Fig. 4. This microneedle 15 is cone-shaped, tapering from the base 13 to an outer tip 16. In this form, the functional substance is distributed within the material of the microneedle 15. [0038]

To facilitate severing or breaking off the outer portion of a microneedle in the skin, the microneedle 17 of Fig. 5 is formed with a conical outer portion and a constriction 20 between the ends of the microneedle to facilitate breaking off the outer portion 18 at the constriction 20 upon manipulation of the base 13. [0039]

An alternative form of a microneedle that is formed to facilitate severing or breaking off the outer portion is illustrated in Fig. 6. In this embodiment the microneedle 21 is formed with a conical outer portion 22 and an enlarged cylindrical inner portion 23, with the intention that the outer portion 22 will break off from the inner portion 23 upon manipulation of the base 13. Figure 7 illustrates a similar needle 24 in which the inner portion 23' is tapered. [0040]

Another alternative shape of the microneedle is illustrated in Figs. 8 and 9. In this embodiment the microneedle 25 is formed as a three-sided tapered prism. [0041]

Paragraph 42 Rather than having the functional substance distributed in the material of the microneedle 14, the functional substance may be carried by the microneedle 14, such as in a recess, with the functional substance being retained in the recess by capillary attraction or by being encapsulated in a dissolvable or otherwise disintegratable microcontainer. Concentrating the functional substance in a recess rather than distributing the functional substance in the material of the microneedle and base, requires more complicated manufacture, but may be necessary where the functional material is not compatible with mixing in the main material of the microneedle, and may be preferable where the functional substance is expensive and significant amounts would be wasted in the base that is not inserted into the skin. [0042]

A microneedle 26 carrying the functional substance separately is illustrated in Figs. 10 and 11. In this embodiment, the functional substance 27 is encapsulated in a spherical

microcontainer 28, which is embedded in the barbed tip 29 of the microneedle 26. This barbed tip 29 configuration also facilitates separation of the tip 29 when the base 13 is removed from the skin. The microcontainer 28 may preferably be made from the same sugars or other material as the material of the microneedle 26. It can be used with substances such as insulin or vitamin C or substances that are not compatible with the microneedle material or are too expensive for use if they were mixed throughout the microneedle material. [0043]

Capillary retention of the functional substance in a microneedle is illustrated in Figs. 12 and 13. In this embodiment, the microneedle 31 is in the shape of a truncated cone. A cylindrical recess 32 is formed in the microneedle 31 extending from an open end 33 centrally along the axis of the microneedle through the full length of the microneedle 31. In this embodiment, a functional substance 34 is retained in the recess 32 and is released into the stratum corneum or dermis upon disintegration of the material of the microneedle 31. Typically, such a recess may be 10-100μm in diameter. [0044]

To facilitate painless insertion of the microneedles into the skin, particularly with the longer needles that are intended to penetrate the dermis, the tips of the needles may be formed as knife points as illustrated in Figs. 14 a, b, c and d. The needle point 36 illustrated in Fig. 14a tapers sharply on all sides to a sharp tip 37 with the recess 38 opening at a spacing from the tip 37 so as not to result in any blunting of the tip. The needle point 39 illustrated in Fig. 14b has one side 40 that tapers sharply to a sharp edge 41 at the top of an opposite side, with the recesses 42 opening along the side 40 short of the sharp edge 41 so as not to interfere with the sharp edge 41. The needle point 43 illustrated in Fig 14c is formed on the end of a cylindrical or conical microneedle 44 with an inclined surface 45 that inclines sharply to an outer tip 46, with the recess 47 opening along the inclined surface 45. The needle point 48 illustrated in Fig. 14d is

bifurcated, formed by a U-shaped cut 49 in the outer end of a cylindrical or conical microneedle 50 with inclined surfaces 51 that incline to sharp tips 52. The recess 53 opens into the base of the U-shaped cut 49. [0045]

The applicator 10 is preferably produced by first creating a master pattern by using synchrotron x-ray radiation through a mask with a specific pattern to irradiate an x-ray sensitive photopolymer foundation containing polymethyl methacrylate, which is then developed to eliminate the irradiated portion. This is preferably done with the microfabrication technology disclosed in Japanese Patent No. 2002151395, dated May 24, 2002, the substance of which is incorporated herein by reference. This technology is further developed, making micron-size high precision processing easy by applying ultra-short wave length x-rays produced by the synchrotron x-ray radiation. A mold is then formed from the master pattern using a process such as electrotyping or machine processing, which forms a reverse profile to that of the master pattern. The mold may be made, for example, from nickel, titanium, stainless steel, or any other suitable material or alloy. [0046]

For microneedles of the larger size that are used to insert into the dermis, the pattern may be made by ultraviolet lithography in which an ultraviolet photopolymer is irradiated by ultraviolet rays. [0047]

After forming the mold, the material of the microneedle 14 and base 13 is formed in the mold by injection molding or casting to produce the final integral microneedle 14 and base 13 product. [0048]

The applicator 10 or a plurality of applicators may be retained temporarily on the skin by fixing the applicators 10 on an adhesive tape 35, such as medical tape, as illustrated in Fig. 3, and adhering the tape 11 onto the skin. [0049]

The following examples disclose ways in which the present invention may be practically utilized, but it is understood that these examples are not limiting as the present invention has application in many other ways that would be appreciated by one skilled in the art. [0050]

Example 1

The applicator is used to mask or eliminate a discolored or undesirably colored portion of the skin of a face. The microneedle and base material is produced with a functional cosmetic powder of a similar color to the test subject's skin distributed homogeneously in the material of the microneedle. Multiple applicators can be utilized where the area to be treated is relatively large. As the normal thickness of a skin's stratum corneum is normally over 100μm and under 300μm, a microneedle height of 50μm to 70μm is used with the width of the tip being under 5μm to avoid inflicting any pain. [0051]

Ten thousand 60μm long, 10μm diameter conical needles formed of maltose, mixed with 20% by weight of a functional cosmetic powder, were created according to the production method described hereinabove and were formed on a 1cm square base 35. [0052]

The applicator was lightly applied to the test subject's facial area, tapped by hand about 10 times, and the base removed, leaving the microneedles, or at least outer portions of the microneedles, in the skin. This treatment eliminated any visual difference in appearance from the surrounding skin area. [0053]

A variation of this example uses a conical microneedle 150μm in length of a diameter at the base of 50μm and a diameter at the tip of 5μm. It uses a material comprising 95% maltose, 3% dextran and 2% vitamin C. [0054]

Example 2

There is a potential problem in misidentifying new born babies with the tragic result of babies being associated with the wrong mother. In an attempt to avoid such mishaps, ribbons, pen markings and labels are used, but these are frequently lost during handling or movement of the newborns. In this example, markings can be implanted in the stratum corneum of a newborn's skin to provide a safely retained identification unaffected by handling or activity of the newborn. [0055]

In this example, 2,500 70μm long, 20μm diameter conical microneedles formed of maltose material mixed with 15% by weight of red food coloring were created according to the production method described above, on a 0.5cm square base. The applicator was lightly applied to the test subject's skin (for test purposes, an adult subject was used, rather than a new born) and tapped by hand about 10 times. The base was then removed. A 0.5cm square red color marking resulted. The red coloring remained until it completely disappeared after approximately two months. [0056]

Example 3

In the field of entertainment, actors and other performers often desire skin markings that replicate beauty marks or otherwise provide a desirable effect. There is, therefore, a high demand for reproducibility in makeup techniques, which can be obtained easily and quickly by the present invention. New methods of expression can thus be provided, supporting the

creation of a new entertainment culture, which technique can also be utilized for effect by the public at large. [0057]

For this purpose, an applicator may be produced having 60μm long 15μm diameter circular needles formed from maltose mixed with 10% by weight of India ink, formed on a 0.3cm diameter circular base. This would be lightly applied to the back of a hand of a test subject, tapped by hand about 10 times and then removed, leaving portions of the microneedles in the skin. As a result, a 0.3cm diameter circular beauty mark would be easily created without pain to the test subject. It is expected that a beauty mark would result that would remain for approximately 3 months. [0058]

Example 4

Cosmetic powders or oils are conventionally used on the face or other parts of the body as a sun block, but these often lose there effectiveness as they are easily removed through sweating, bathing, washing or other contact with foreign objects. By the present example, sun block material can be implanted shallowly in the face or body skin otherwise to provide a sun block that can be sustained for a few days, making it far more effective than conventionally applied sun block products. [0059]

For this purpose, 70μm long, 10μm diameter conical microneedles are formed of maltose mixed with 1% by weight of parasol MCX (octylmethoxycinnamate), an organic ultraviolet shield. The microneedles are formed on a 1cm diameter circular base. This was lightly applied to the back of the hand of the test subject, tapped by hand about 10 times, and then removed, leaving portions of the microneedles in the stratum corneum. For the following month, the test subject exposed the back of the hand to direct outdoor sunlight and the extent of sunburn was

examined. The result was that a 1cm diameter circular portion of the skin was not as sunburned as the surrounding parts and there was no sunburn sensation experienced by the test subject in that area. The sun block effect disappeared after approximately 2-1/2 months. [0060]

As established by the foregoing examples, the applicator of the present invention can be used to apply functional cosmetic powders, such as artificial colorings, such as ultraviolet absorbers, and the functional substance can be inserted into the skin's stratum corneum by leaving the tip or part of the microneedle within the skin. The main material of the microneedles being sugar, the portions of the microneedles that remain in the skin disintegrate and disperse into the skin and ultimately into the body, being harmless to the body. The functional substance will be maintained in the skin from a few days to a few months. Thus, the use of the applicator of the present invention is painless, safe, effective and easily applied. [0061]

Example 5

It is contemplated that aspirin (acetylsalicylic acid) can be mixed in sugar material in a ratio of 95% maltose, 3% dextran and 2% aspirin and formed into needles, such as illustrated in Fig. 4, 1,000μm long, 500μm in diameter at the base and 5μm in diameter at the tip. [0062]

By the present invention, functional substances can be implanted into the skin in a painless manner with the substance being applied in a stable condition during the skin's renewal process, allowing the functional substance to remain in the stratum corneum for extended periods of time, obviating the necessity to repeatedly apply functional substances topographically to the skin on a daily basis. Further, by using sugars as the material for the

microneedles, the material is dissipated within the skin and even within blood vessels if the insertion is accidentally to a greater depth than intended, making the application safe. Further, when applied to the depth of the dermis, a substance that is capable of disintegrating into the body can do so readily. If the substance is not disintegratable, such as tattoo material, it will remain substantially permanently if applied into the dermis. [0063]

VI. Grounds of Rejection to be Reviewed on Appeal.

(1). Rejection in the final Office Action of Claims 1-10, 14-16, 19-32 and 34 under 35 U.S.C. 103 (a) as being unpatentable over Park, et al. (Pub. No. US 2002/0082543 A1) in view of D'Ussel (Pub. No. US 20040010237 A1).

(2). Rejection in the final Office Action of Claim 6 under 35 U.S.C. 103 (a) as being unpatentable over Park.

(3). Rejection in the final Office Action of Claims 12, 13 and 32 as being unpatentable over Park in view of Arias, et al. (Pub. No. 20020133129 A1).

(4). Rejection in the final Office Action of Claims 17 and 18 under 35 U.S.C. 103 (a) as being unpatentable over Park in view of Sherman, et al. U.S. Patent No. 6,821,281.

VII. Argument.

(1). Rejection in the final Office Action of Claims 1-10, 14-16, 19-32 and 34 under 35 U.S.C. 103 (a) as being unpatentable over Park, et al. (Pub. No. US 2002/0082543 A1) in view of D'Ussel (Pub. No. US 20040010237 A1).

Claim 1 reads as follows:

Claim 1. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is substantially sugars that dissolve within the human body and capable of disintegration and dispersion into the skin, and

(c) a functional substance carried by said microneedles for delivery by said microneedles into the skin.

In rejecting Claim 1, the final Office Action of November 2, 2005, states that the Park reference describes the subject matter of Claim 1, except that it does not disclose that the needles are made of a material that is substantially sugars that dissolve in the human body. The Office Action then states that the D'Ussel reference describes a needle made substantially of sugars that dissolves within the human body, and that it would be obvious to modify the Park microneedles with the sugar needle of D'Ussel.

The fallacy in this is that D'Ussel does not disclose "a needle made substantially of sugars" or a "sugar needle." D'Ussel discloses no more than a sharp tip that can be made of a sugar or other material that serves as a closure at the tip of a metal needle (Paragraphs 12, 16, 18, and 19).

The accompanying Declaration of Dr. Ajay K. Banga establishing unobviousness is authored by a prestigious expert in the field as evidenced by the twenty-eight page Curriculum Vitae which chronicles the vast experience of the Declarant, Dr. Banga, in the field of transdermal delivery and microporation. From his Curriculum Vitae it is clear that Dr. Banga is

well qualified to render an opinion as to the unobviousness of the subject matter of the claims of the present application.

Mercer University, by whom Dr. Banga is employed, purchases microneedles from one of the Assignees of the present application at a standard university research price for academic research by Dr. Banga in experimentations in applying various drug materials. Other than sharing non-confidential research results, neither Mercer University nor Dr. Banga have any relation to the present inventors or their Assignees.

The reasons for Dr. Banga's opinion of unobviousness of the subject matter of Claim 1 are cogently recited in Paragraphs 7-11 of the Declaration, the substance of which are adopted herein. These paragraphs state as follows:

> 7. This feature of microneedles made substantially of sugar that dissolves within the human body and disintegrates and disperses into the skin for depositing of functional substances into the skin is not disclosed or suggested or obvious from the teachings of the Park and D'Ussel patents.
>
> 8. The Park patent does not teach or suggest microneedles made of sugar material. Rather, the Park patent teaches the use of polymers, metals, ceramics, semi-conductor materials and composites. Polymer needles made of biodegradable polymers such as PLGA will release drug very slowly over a period of time to provide sustained drug delivery. This would be a very different application as compared to the present invention where sugar microneedles can quickly dissolve in the skin to provide instant (bolus) drug delivery. Using just a sugar tip from a conventional needle and extrapolating that information to make an all-sugar microneedle will not be obvious to somebody skilled in this art, and also the manufacturing methods will be entirely different.
>
> 9. The D'Ussel patent discloses metal, not sugar, microneedles with only a pointed tip of sugar that serves as a seal for temporarily retaining injection liquids in the needles. The tips are formed by vertically immersing the needles in a hot solution of material, which may be sugar, and then raising the needles so that a sharp point is formed. There is no way that an entire microneedle can be formed in this manner as there must be a substantial portion of the microneedle formed

of metal or rigid material on the end of which a drop of sugar can be formed to provide a sharp tip. Dipping a flat base or only partially formed microneedles in a hot bath and removing them would not conceivably result in a needlelike formation.

10. In addition, D'Ussel teaches sterilization of the needles, which would destroy any sugar formulation.

11. The D'Ussel patent does not teach or suggest the use of microneedles and particularly the use of sugar tips on microneedles. Rather, D'Ussel teaches applying tips to conventional needles. There is no known technique for dipping microneedles into a hot sugar solution and having tips formed on the microneedles when the microneedles are removed from the bath. Also, microneedles are very different from conventional needles. The former is a very recent innovative approach to drug delivery while the later has been used for a very long time.

For these reasons, it is respectfully submitted that the opinion of one highly skilled in the art should be accepted to establish that the subject matter of Claim 1 is unobvious and that Claim 1, along with its dependent Claims 2-10 and 12-32 are allowable.

Claim 14 reads as follows:

Claim 14. An applicator according to claim 1 and characterized further in that said microneedles have tips that are knife-shaped to facilitate insertion into the skin.

Claim 14 is rejected as being anticipated by Park, with reference to Figure 5 of Park. However, Claim 14 recites that the tips of the microneedles are knife-shaped. The microneedles shown in Figure 5 of Park are not knife-shaped. They appear to be conical. Therefore, Park does not anticipate the subject matter of Claim 14.

Claim 15 reads as follows:

Claim 15. An applicator according to claim 1 and characterized further by microcontainers containing said functional substance, said microcontainers being contained within said microneedles for delivery into the skin.

Claim 15 recites that the applicators have microcontainers containing functional substance and being contained within the microneedles. The Office Action rejects Claim 15 on the basis of Park, with reference to Figure 3. However, Figure 3 of Park illustrates a layered

microneedle. In Paragraph 0023 of Park, the microneedle is disclosed as being formed of multiple layers, not microcontainers. There is no teaching or suggestion in Park of the use of microcontainers contained in microneedles. Therefore, Park does not anticipate the subject matter of Claim 15.

Claim 16 reads as follows:

Claim 16. An applicator according to claim 15 and characterized further in that said microneedles are formed with barbed tips and said microcontainers are disposed in said barbed tips for separation with the barbed tips from the remainder of the microneedles for retention in the skin upon removal of the base.

Claim 16 depends from Claim 15 and is not anticipated by Park for the same reasons. Further, Claim 16 includes microneedles with barbed tips in which the microcontainers are disposed for separation with the barbed tips from the remainder of the microneedles. The Office Action rejects Claim 16 on the basis of Figure 3 of Park. However, not only is there no microcontainer in Figure 3 of Park, but there are no barbed tips. Rather, the tips of the microneedles of Figure 3 of Park are simply conical continuations of the remainder of the microneedles. Therefore, Park does not anticipate the subject matter of Claim 16.

Claim 31 reads as follows:

Claim 31. An applicator according to claim 1 and characterized further in that said material is substantially maltose.

Claim 31 recites that the material of the microneedles is substantially maltose. Therefore, Claim 31 is allowable for the same reasons as Claim 1 and further because maltose is not disclosed or suggested in any of the cited prior art.

The Office Action rejects Claim 33 as being obvious over the Park reference in view of the D'Ussel reference, without explanation. It may be that the Examiner intended to include a

rejection of Claim 33 with the rejection of Claims 13 and 32 based on the combination of the Park reference in view of Arias et al. (US 2002/0133129 A1), referring to Figure 15I of Arias.

Rejected Claim 33 reads as follows:

Claim 33. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and dispersion into the skin,

(c) a functional substance carried by said microneedles for delivery by said microneedles into the skin, and

(d) said microneedles having relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

Claim 33 recites the subject matter of original Claim 1, without the limitation to the material being substantially sugars, and adds the structure of the microneedles having relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of the outer portions from the inner portions with the outer portions remaining in the skin. The preferred embodiment of this subject matter is illustrated in Figure 5 of the drawings of this application. This configuration in combination with the microneedles of a material that is capable of disintegration and dispersion into the skin provides a unique and advantageous result in that when the microneedles are applied to the skin the base and the inner portions of the attached microneedles can be removed, leaving the outer portions, in which the functional material is dispersed, in the skin for disintegration and dispersion. The base and inner portions of the microneedles need not be retained in position on the skin while the outer portions are disintegrating.

As pointed out in the Banga Declaration, there is nothing disclosing or suggesting this feature in the cited references. Arias discloses no restricted intermediate portion between outer and inner portions that would facilitate separation of the outer portion from the inner portion. Rather, Figure 15I discloses nothing other than a tapering stepped configuration with each portion outwardly of an inner portion being sequentially reduced. The purpose of this, as explained in the Arias reference, is to produce a sharp-pointed needle. It has nothing to do with forming a needle in a structure in which an outer portion can be readily separated from an inner portion, leaving the outer portion in the skin.

Therefore, the subject matter of Claim 33 is clearly not rendered obvious from the combination of the Park and Arias references.

Independent Claim 34 reads as follows:

Claim 34. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and dispersion into the skin, and

(c) microcontainers containing said functional substance, said microcontainers being contained within said microneedles for delivery into the skin.

Claim 34 recites the same subject matter of original Claim 1, without the "substantially sugar" limitation of present Claim 1, and adds the feature of microcontainers containing the functional substance and themselves being contained within the mirconeedles for delivery into the skin. This claim was rejected in the Office Action on the basis of Figure 3 of the Park reference disclosing microcontainers within microneedles. However, as pointed out in the Banga Declaration, Figure 3 of the Park reference has nothing to do with microcontainers.

Rather, it discloses a sequence of layers of material forming the microneedle. None of these layers are microcontainers and none of them are contained within the microneedles, but rather extend fully across the microneedles and form the microneedles themselves rather than being a container within a microneedle.

There is nothing in the Park reference that suggests having microcontainers within microneedles. Therefore, the subject matter of Claim 34 and its dependent Claim 35, is unobvious.

Claim 35 also was rejected only generally as being obvious over the Park reference in view of D'Ussel reference without explanation.

Claim 35 reads as follows:

Claim 35. An applicator according to claim 34 and characterized further in that said microneedles are formed with barbed tips and said microcontainers are disposed in said barbed tips for separation with the barbed tips from the remainder of the microneedles for retention in the skin upon removal of the base.

Claim 35 depends from Claim 34 and adds the feature of the microcontainers disposed in barbed tips of the microneedles as recited in Claim 16. Therefore, Claim 35 is patentable over the cited prior art for the same reasons as discussed above with regard to this feature in Claim 16.

(2). Rejection in the final Office Action of Claim 6 under 35 U.S.C. 103 (a) as being unpatentable over Park.

Claim 6 depends from Claim 5, which in turn depends from Claim 1. Therefore, Claim 6 is patentable for the reason that it incorporates by reference the patentable subject matter of Claim 1.

(3). Rejection in the final Office Action of Claims 12, 13 and 32 as being unpatentable over Park in view of Arias, et al. (Pub. No. 20020133129 A1).

Claim 12 reads as follows:

Claim 12. An applicator according to claim 1 and characterized further in that said microneedles are constricted intermediate their ends to facilitate breaking off the portions of the needles beyond the narrow portions to leave those portions in the skin.

In addition to being allowable on the basis of depending from Claim 1, Claim 12 further recites that the microneedles are restricted intermediate there ends to facilitate breaking off the portions of the needles beyond the narrow portions to leave these portions in the skin. The Office Action rejects Claim 12 on the basis of Park in view of Arias U.S. Patent Publication No. 2002/0133129 A1. However, Arias, which is relied on by the Examiner as disclosing microneedles constricted intermediate there ends with reference to Figure 15L, does not disclose a restriction intermediate the ends of microneedles. Rather, Arias, in Figure 15L discloses needles that progressively become smaller from the base to the tip. The tips are the portions of the Arias needles that are restricted in relation to the other portions. There is no restriction intermediate the ends in Arias, rather the restriction progresses to the end and there is no portion beyond the narrowest portion that could possibly break off and remain in the skin. Further, there is no teaching or suggestion otherwise in the Arias reference. In addition, Paragraph 0171 of Arias discloses that the needles may be metallic, which obviously would be hazardous if broken off and left in the skin, contrary to the purpose of dissolvable sugar portions being left in the skin according to the present invention.

Claim 13 reads as follows:

Claim 13. An applicator according to claim 1 and characterized further in that said microneedles have relatively thin outer portions and relatively thick inner portions adjacent said base with a step between said portions to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

Claim 13 depends from Claim 1 and is allowable for the same reasons as Claim 1. In addition, Claim 13 recites a structure that facilitates separation of the outer portions of the microneedles from the inner portions with the outer portions remaining in the skin. There is no structure in the Arias reference that results in outer portions remaining in the skin. Rather, as pointed out above, it would be hazardous if the outer portion of the Arias needle remained in the skin.

Claim 32 reads as follows:

Claim 32. An applicator according to claim 1 and characterized further in that said microneedles have relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

Claim 32 depends from Claim 1 and adds that the microneedles are formed with relatively thick inner and outer portions with restricted intermediate portions to facilitate separation of the outer portions. Therefore, Claim 32 is allowable for the same reasons as Claim 1 and further because there is no disclosure or suggestion in the prior cited patents of relatively thick inner and outer portions with constricted intermediate portions that facilitate separation of the outer portions for remaining in the skin. No specific explanation for the rejection of Claim 33 was given in the final Office Action. However, Claim 33 incorporates the same thick inner portions, relatively thick outer portions and constricted intermediate portions feature of Claim 32 and is allowable for the same reasons as Claim 32.

Incidentally, Claim 32 was rejected on two different, unrelated, grounds. Apparently, there was a mistake in rejecting Claim 32 on the basis of prior art that showed a cone shape as Claim 32 has nothing to do with a cone shape.

(4). Rejection in the final Office Action of Claims 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Park in view of Sherman, et al. U.S. Patent No. 6,821,281.

Claims 17 and 18 read as follows:

Claim 17. An applicator according to claim 1 and characterized further in that said microneedles have capillary recesses in outer portions thereof for retaining said functional substances for delivery into the skin.

Claim 18. An applicator according to claim 17 and characterized further in that said capillary recesses extend along a central axis of said microneedles and are open at the outer ends of said microneedles.

Claims 17 and 18 depend from Claim 1 and are allowable for the same reasons.

VIII. Conclusion.

Therefore, for all the aforementioned reasons, it is respectfully submitted that the rejection of the pending claims be reversed and that the claims be found allowable.

Enclosed herewith is a fee of $250.00 for filing this appeal brief. The Commissioner is authorized to charge any other fee which is due or to credit any fee overpayment which has been made to Deposit Account No. 18-1215.

Respectfully submitted,

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Claims with Entered Amendments

Claim 1. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is substantially sugars that dissolve within the human body and capable of disintegration and dispersion into the skin, and

(c) a functional substance carried by said microneedles for delivery by said microneedles into the skin.

Claim 2. An applicator according to claim 1 and characterized further in that said functional substance is distributed in the material of said microneedles.

Claim 3. An applicator according to claim 2 and characterized further in that said functional substance is distributed homogeneously throughout said microneedles.

Claim 4. An applicator according to claim 1 and characterized further in that said functional substance is encapsulated in said microneedles.

Claim 5. An applicator according to claim 1 and characterized further in that said base and said microneedles are integrally molded from the same material.

Claim 6. An applicator according to claim 5 and characterized further in that said functional substance is distributed homogeneously throughout said base and microneedles.

Claim 7. An applicator according to claim 1 and characterized further in that said microneedles are generally cone shaped.

Claim 8. An applicator according to claim 1 and characterized further in that said microneedles are square in cross-section.

Claim 9. An applicator according to claim 1 and characterized further in that said microneedles are polygonal in cross-section.

Claim 10. An applicator according to claim 1 and characterized further in that said microneedles are at least partially elliptical in cross-section.

Claim 12. An applicator according to claim 1 and characterized further in that said microneedles are constricted intermediate their ends to facilitate breaking off the portions of the needles beyond the narrow portions to leave those portions in the skin.

Claim 13. An applicator according to claim 1 and characterized further in that said microneedles have relatively thin outer portions and relatively thick inner portions adjacent said base with a step between said portions to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

Claim 14. An applicator according to claim 1 and characterized further in that said microneedles have tips that are knife-shaped to facilitate insertion into the skin.

Claim 15. An applicator according to claim 1 and characterized further by microcontainers containing said functional substance, said microcontainers being contained within said microneedles for delivery into the skin.

Claim 16. An applicator according to claim 15 and characterized further in that said microneedles are formed with barbed tips and said microcontainers are disposed in said barbed tips for separation with the barbed tips from the remainder of the microneedles for retention in the skin upon removal of the base.

Claim 17. An applicator according to claim 1 and characterized further in that said microneedles have capillary recesses in outer portions thereof for retaining said functional substances for delivery into the skin.

Claim 18. An applicator according to claim 17 and characterized further in that said capillary recesses extend along a central axis of said microneedles and are open at the outer ends of said microneedles.

Claim 19. An applicator according to claim 1 and characterized further in that said microneedles project from said base a distance sufficient to penetrate the stratum corneum.

Claim 20. An applicator according to claim 19 and characterized further in that said microneedles project approximately 0.5 to 500μm from said base.

Claim 21. An applicator according to claim 20 and characterized further in that said microneedles are generally cone shaped with the diameter at said base being approximately 0.1 to 100μm.

Claim 22. An applicator according to claim 20 and characterized further in that said microneedles are square in cross-section with the sides being approximately 0.1 to 100μm at said base.

Claim 23. An applicator according to claim 20 and characterized further in that said microneedles are polygonal in cross-section with the sides being approximately 0.1 to 100μm at said base.

Claim 24. An applicator according to claim 20 and characterized further in that said microneedles are at least partially elliptical in cross-section with a shortest diameter of 0.1 to 100μm at said base.

Claim 25. An applicator according to claim 1 and characterized further in that said microneedles project from said base a distance sufficient to penetrate the dermis.

Claim 26. An applicator according to claim 25 and characterized further in that said microneedles project approximately 500 to 5,000μm from said base.

Claim 27. An applicator according to claim 26 and characterized further in that said microneedles are generally cone shaped with the diameter at said base being approximately 0.1 to 1,000μm.

Claim 28. An applicator according to claim 26 and characterized further in that said microneedles are square in cross-section with the sides being approximately 0.1 to 1,000μm at said base.

Claim 29. An applicator according to claim 26 and characterized further in that said microneedles are polygonal in cross-section with the sides being approximately 0.1 to 1,000μm.

Claim 30. An applicator according to claim 25 and characterized further in that said microneedles are at least partially elliptical in cross-section with a shortest diameter of 0.1 to 1,000μm at said base.

Claim 31. An applicator according to claim 1 and characterized further in that said material is substantially maltose.

Claim 32. An applicator according to claim 1 and characterized further in that said microneedles have relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

Claim 33. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and dispersion into the skin,

(c) a functional substance carried by said microneedles for delivery by said microneedles into the skin, and

(d) said microneedles having relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

Claim 34. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and dispersion into the skin, and

(c) microcontainers containing said functional substance, said microcontainers being contained within said microneedles for delivery into the skin.

Claim 35. An applicator according to claim 34 and characterized further in that said microneedles are formed with barbed tips and said microcontainers are disposed in said barbed tips for separation with the barbed tips from the remainder of the microneedles for retention in the skin upon removal of the base.

MERCER UNIVERSITY
SOUTHERN SCHOOL OF PHARMACY
Department of Pharmaceutical Sciences

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of:

Serial No.: 10/666,581
Yoshikazu Tobinaga et al.
Filed: September 18, 2003
Group Art Unit: 3763
Examiner: Aamer S. Ahmed

For: APPLICATOR FOR APPLYING FUNCTIONAL SUBSTANCES INTO HUMAN SKIN

Atlanta, Georgia February 8, 2006

DECLARATION OF DR. AJAY K.BANGA

I, Dr. Ajay K. Banga, am a professor and the Chair of the Department of Pharmaceutical Sciences at Mercer University, Atlanta, Georgia.

I do hereby declare as follows:

1. A summary of my professional background is attached as Exhibit A.

2. I have had extensive experience in the field of transdermal delivery and microporation. My basis for making this patent declaration is my over 20 years of experience as an experimental scientist in the field of transdermal delivery, the last 14 (since obtaining my Ph.D. in pharmaceutics at Rutgers – The State University of New Jersey), as an Assistant Professor and Associate Professor (tenured) at Auburn University in Alabama, and then as an Associate Professor and Professor at Mercer University in Atlanta, Georgia. I also serve as the Chairman of the Department of Pharmaceutical Science at Mercer University. In my career, I have had over fifty publications in leading refereed pharmaceutical journals, authored two single author books, which have been cited extensively by leading researchers in national and international literature. One of these books relates to transdermal delivery. In addition to this, I have contributed to over seventy-five (75) presentations at scientific meetings such as national meetings of the Controlled Release Society and the American Association of Pharmaceutical Scientists (AAPS). I have worked with skin microporation technology (thermal microporation) for the last 5 years with Altea Therapeutics and am very familiar with the literature and research groups working with microneedles. I serve on the Scientific Advisory Board of three companies and as a consultant to several companies. I have been invited to give lectures on transdermal delivery for numerous governmental, industrial, and academic institutions, both in the

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United States and abroad, such as the Food and Drug Administration (FDA), the Georgia Institute of Technology, King's college London, Ciba Geigy Basel, and the Indian Institute of Technology in New Delhi. I was appointed the Editor-in-Chief for the journal *Critical Reviews in Therapeutic Drug Carrier Systems* in 2002 and am on the editorial advisory board of *PharmSci* (an AAPS electronic journal). I am a frequent reviewer on transdermal delivery and have published or preparing manuscripts for such prestigious journals as the *American Journal of Drug Delivery*, the *Journal of Controlled Release,* the *European Journal of Pharmaceutical Sciences,* the *International Journal of Pharmaceutics*, the *Journal of Pharmaceutical Sciences*, and *PharmSci,* a journal of the AAPS. I have received several grants/contracts in the area of transdermal delivery. I also review research proposals for grant committees, including the National Institutes of Health (NIH). Please see my attached CV for a more complete summary of my credentials (Exhibit A).

3. In preparation for making this Declaration, I have reviewed a copy of U.S. Patent Application No. 10/666,581 as originally filed; a copy of an Amendment and Response filed September 15, 2005 in the application; a copy of an Office Action dated November 2, 2005, issued by the U.S. Patent and Trademark Office in that application; a copy of Park et al. U.S. Patent Application Publication No. U.S. 2002/0082543 A1;a copy of D'Ussel U.S. Patent Application Publication No. U.S. 2004/0010237 A1

4. I have studied Claim 1 as it appears in the Amendment and Response of September 15, 2005, and compared it in detail with the subject matter of the Park and D'Ussel Patent Publications, and I have also considered the reasons stated in the Office Action of November 2, 2005, for rejecting Claim 1 as being obvious based on the combination of the Park and D'Ussel Publications.

5. Claim 1 as set out in the Amendment and Response of September 15, 2005, reads as follows:

Claim 1. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is substantially sugars that dissolve within the human body and capable of disintegration and dispersion into the skin, and

(c) a functional substance carried by said microneedles for delivery by said microneedles into the skin.

6. Having microneedles made of a material that is substantially sugar that dissolves within the human body and are capable of disintegration and dispersion into the skin is a unique feature having the advantage, unexpected, with other microneedles, of delivering functional substances into the skin with the disintegration and dispersion resulting in dissemination of the functional substances without requiring any further physical act to separate the functional substances from the microneedles into the skin.

7. This feature of microneedles made substantially of sugar that dissolves within the human body and disintegrates and disperses into the skin for depositing of functional substances into the skin is not disclosed or suggested or obvious from the teachings of the Park and D'Ussel patents.

8. The Park patent does not teach or suggest microneedles made of sugar material. Rather, the Park patent teaches the use of polymers, metals, ceramics, semi-conductor materials and composites. Polymer needles made of biodegradable polymers such as PLGA will release drug very slowly over a period of time to provide sustained drug delivery. This would be a very different application as compared to the present invention where sugar microneedles can quickly dissolve in the skin to provide instant (bolus) drug delivery. Using just a sugar tip from a conventional needle and extrapolating that information to make an all-sugar microneedle will not be obvious to somebody skilled in this art, and also the manufacturing methods will be entirely different.

9. The D'Ussel patent discloses metal, not sugar, microneedles with only a pointed tip of sugar that serves as a seal for temporarily retaining injection liquids in the needles. The tips are formed by vertically immersing the needles in a hot solution of material, which may be sugar, and then raising the needles so that a sharp point is formed. There is no way that an entire microneedle can be formed in this manner as there must be a substantial portion of the microneedle formed of metal or rigid material on the end of which a drop of sugar can be formed to provide a sharp tip. Dipping a flat base or only partially formed microneedles in a hot bath and removing them would not conceivably result in a needlelike formation.

10. In addition, D'Ussel teaches sterilization of the needles, which would destroy any sugar formulation.

11. The D'Ussel patent does not teach or suggest the use of microneedles and particularly the use of sugar tips on microneedles. Rather, D'Ussel teaches applying tips to conventional needles. There is no known technique for dipping microneedles into a hot sugar solution and having tips formed on the microneedles when the microneedles are removed from the bath. Also, microneedles are very different from conventional needles. The former is a very recent innovative approach to drug delivery while the later has been used for a very long time.

12. For the foregoing reasons, it is my firm opinion that the subject matter of Claim 1 of U.S. Patent Application No. 10/666,581 would not have been obvious to someone ordinarily skilled in the art from the teachings or suggestions of the Park and D'Ussel patents.

13. Claim 33 of U.S. Patent Applications 10/666,581, as appears in the Amendment and Response, dated September 15, 2005, reads as follows:

Claim 33. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and

dispersion into the skin,

(c) a functional substance carried by said microneedles for delivery by said microneedles into the skin, and

(d) said microneedles having relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

14. Claim 33 features a microneedle construction where there are relatively thick inner and outer portions with constricted intermediate portions, with the intermediate portions facilitating separation of the outer portions from inner portions so that the outer portions will break off and be retained in the skin. As the microneedles are of a material that is capable of disintegration and dispersion into the skin, the outer portions will be dissipated into the skin without any lasting harm. Further, the outer portions can contain the functional substance that is to be dispersed into the skin, which can occur effectively as the outer portions that have been left in the skin disintegrate.

15. There is no teaching or suggestion in the Park and D'Ussel patent applications of this restricted intermediate portion between outer and inner portions that facilitate breaking off of the outer portion. Rather, the Park and D'Ussel patents disclose and suggest nothing other than conventional needles that taper generally from a larger base to a smaller tip.

16. Therefore, it is my opinion that the subject matter of Claim 33 of U.S. Patent Application No. 10/666,581 would not be obvious to one ordinarily skilled in the art from the Park and D'Ussel patents.

17. Claim 34 of U.S. Patent Application Serial No. 10/666,581 as presented in the Amendment and Response of September 15, 2005, reads as follows:

Claim 34. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and dispersion into the skin, and

(c) microcontainers containing said functional substance, said microcontainers being contained within said microneedles for delivery into the skin.

18. The significant feature of Claim 34 is the inclusion of microcontainers containing functional substances with the microcontainers being contained within microneedles for delivery into the skin upon disintegration and dispersion of the microneedles.

19. This feature is not disclosed or suggested in either the Park or D'Ussel patents or any obvious combination thereof

20. The Office Action of November 2, 2005, refers to the disclosure of Figure 3 of Park as disclosing this feature. However, Figure 3 of the Park patent publication has nothing to do with microcontainers. It discloses different layers of material, none of which are microcontainers. These layers extend completely across the microneedles and do not provide any interior container. There is no microcontainer disclosed or suggested in the D'Ussel patent publication.

21. Therefore, it is my opinion that the subject matter of Claim 34 of U.S. Patent Application Serial No. 10/666,581 would not be obvious from any combination of the Park and D'Ussel patent publications.

I further declare that statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements and the like are punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code, and such willful false statements may jeopardize the validity of any patents issued from the patent application.

February 8, 2006

Ajay K. Banga, Ph.D.
Professor & Chair

Exhibit A

CURRICULUM VITA

Ajay K. Banga

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EDUCATION

Doctor of Philosophy (May 1990), Rutgers University, NJ.

Master of Science in Pharmaceutics (Dec. 1986), University of Oklahoma, Oklahoma City, OK.

Masters degree in Pharmaceutics (May 1983), University of Delhi, New Delhi, India.

Bachelors degree in Pharmacy (May 1981), University of Delhi, New Delhi, India

POSITIONS HELD/CHRONOLOGICAL VITA

7/04 - Present	*Chairman*, Dept Pharm Sci, Mercer University, Atlanta, GA
7/03 - Present	*Professor*, Mercer University, Atlanta, GA
3/99 - 6/03	*Associate Professor,* Mercer University, Atlanta, GA *(Tenured effective 7/01)*
9/96 - 2/99	*Associate Professor with Tenure,* Auburn University, AL
8/91 - 9/96	*Assistant Professor*, Auburn University, AL
5/90 - 8/91	*Formulation Scientist* at Bausch & Lomb, Rochester, NY.
8/86 - 5/90	*Ph.D Research* at Controlled Drug-Delivery Research Center, Department of Pharmaceutics, College of Pharmacy, Rutgers - The State University of New Jersey, New Jersey. Also, served as *graduate teaching assistant* (1986-87) and as *graduate fellow* (1987-90).
8/85 - 8/86	*M.S. Research* at Pharmaceutics Division, School of Pharmacy, University of Oklahoma, Oklahoma City, OK. Also, was *graduate teaching assist.*
5/83 - 8/85	*Research Scientist* at Ranbaxy Labs Ltd., N.Delhi, India
5/81 - 5/83	*Masters Research* in pharmaceutics at Univ. of Delhi, New Delhi, India.
5/77 - 5/8	Bachelors degree in pharmacy, Delhi Institute of Pharmaceutical Sciences Research, Univ. of Delhi, N.Delhi, India.

HONORS/PROFESSIONAL

Distinguished Educator Award, School of Pharmacy, Mercer University, Atlanta, GA, presented at the commencement on May 7, 2005.

Received Gateway Research Scholarship from American Foundation for Pharmaceutical Research (AFPE) as faculty advisor for participating student, Adina C. Hirsch., for 2003-04.

Research Award, School of Pharmacy, Mercer University, Atlanta, GA, presented at the commencement on May 5, 2001.

Scientific Advisory Boards

Altea Therapeutics, Atlanta, GA, USA
Transport Pharmaceuticals, Framingham, MA, USA
DiTeba Research Laboratories, ON, Canada

Editorship/Editorial Boards

Editor-in-Chief, Critical Reviews in Therapeutic Drug Carrier Systems 1/02 - present

Editorial advisory boards:

PharmSci (an AAPS electronic journal) 1/99 - present

Critical Reviews in Therapeutic Drug Carrier Systems 1/98 - 12/01

Other Honors

Invited to serve on the following Special Emphasis Panels in Bethesda/Washington area as a reviewer for grants submitted to the National Institutes of Health:

- Center for Scientific Review (CSR), Drug Delivery ZRG 1 SSS-2 (50) Study Section, R01/R21 grants 7/03
- CSR, Hematopoiesis Study section, SBIR/STTR grants, 7/03
- NIH/NIAID program grant applications on control strategies in infectious diseases, 8/02.
- Vaccine study panel to review NIH/NIAID SBIR/STTR/R01 grant applications, 7/01.
- NIH/NIAID grant applications, "Research on Topical Microbicides for the prevention of STDs/HIV", 5/99

Paper presented at the following meetings won the best presentation/poster awards:

- A. Badkar and A. Banga, Effects of formulation pH and buffers on thermal properties and conformational stability of Immunoglobulin G, 24th annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004 (best podium award).

- P. Pendse, R. Bright, R. Durland, C. Wang, and A.K. Banga, Thermal microporation as a novel technique for transdermal immunization with model antigens 24th annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004 (one of the best poster award).

- D.P. Joshi, A. Chaturvedula, S.L. Chang, S.E. Mills, A.M. Smith, and A. K. Banga, Steady infusion of insulin via micropores through the stratum corneum in hairless rats, 24th Annual meeting of the Southeastern pharmacology society, Mercer University, Atlanta, GA, October 16-18, 2003 (third place award for best student podium).

- A. Chaturvedula, R. Conjeevaram, C. Anderson, R. Morris, and A. Banga, Transdermal delivery of propranolol HCl to hairless rats using a self-contained iontophoretic patch, presented at the annual meeting of graduate research association of students in pharmaceutics conference, Richmond, VA, May 30-June 1, 2003 (Best poster award).

- A. Badkar, P. Yohannes, and A.K. Banga, Thermal characterization of protein formulation using modulated temperature differential scanning calorimetry, best presentation award in the Biomedical Sciences at the annual meeting of the Georgia Academy of Sciences, March 21-22, 2003.

- Rajkumar Conjeevaram and Ajay K. Banga, Transdermal iontophoretic delivery of timolol, presented at the 20th Annual Meeting of GRASP, June 2-4, 2000, University of Maryland, Baltimore, Maryland (best poster award).

- Kishore Talluri, Advait Badkar, Srini Tenjarla, and Ajay K. Banga, In Vitro release testing on a peptide gel as per SUPAC-SS recommendations, presented at the *19th Annual Meeting of GRASP, Holiday Inn, Columbia, SC, May 28-30, 1999* (best poster award).

- Manohar Katakam, Leonard N. Bell, and Ajay K. Banga, Role of nonionic surfactants on the stability of recombinant human growth hormone, presented at the *15th Annual Meeting of GRASP, St. John's University, Jamaica, NY, June 2-4, 1995 (best poster award).*

Interviewed (7/99) by "patient care" magazine as an expert/consultant for an article on "drug delivery" (published Jan.2000) intended for physicians - the magazine has a circulation of 125,000 and is targeted to family physicians and general internists nationwide.

Invited (4/97) on the International panel of evaluators for Current Drugs Ltd., a London based company providing expert information on drugs under research and development. Submitted several meeting reports for them.

Graduate student research award to my Ph.D. student, Ms Shu-Lun Chang, for the project, *Transdermal iontophoretic delivery of calcitonin.* Auburn University, AL.

Elected as a full member to Rho Chi and Sigma Xi. Selected for inclusion in Marquis Who's Who in Science and Engineering, 3rd Ed., in press; also in Marquis Who's Who in the South and Southwest, Silver 25th Ed., 1997-98, and 26th Ed (in press) and in Dictionary of International Biograpy, 26th Ed., 1998 (in press).

Media coverage of research activities in Business Georgia magazine (2003/2004), Georgia Trend (2003), and Auburn University Fall 92 Research Update Newsletter and Fall 92 Extension Update Newsletter, and in newspapers in Montgomery, Mobile and Birmingham, Alabama.

Awarded medal by Indian Pharmaceutical Association for First rank in the College of pharmacy, both for bachelors and masters degree in pharmacy, overall and for individual years. Also, secured first rank in pre-medicine year at Hans Raj College, University of Delhi. Served on the executive council of the Indian pharmaceutical association as university representative and on the editorial board of college magazine.

RESEARCH GRANTS/CONTRACTS FUNDED/OTHER FUNDING

Principal and only investigator on the grants unless otherwise specified

Delivery of methotrexate into skin by microneedles, Transport Pharmaceuticals, $ 61,800, November 1, 2005 to October 31, 2007.

Enhancement methods for transdermal delivery of proteins, Pfizer Inc. (New York, NY), $ 150,000, October 15, 2005 to October 14, 2006.

Delivery of sumatriptan succinate by iontophoresis, Travanti Pharma (Oakdale, MN), $ 35,400, September 1, 2005 to August 31, 2006.

Evaluation of drugs for iontophoretic delivery to control acne and psoriasis, Transport Pharmaceuticals (Framingham, MA), $ 100,800, April 18, 2005 to April 17, 2007.

Screening of therapeutic chemical/biological entities for transdermal and/or iontophoretic delivery, Solvay Pharmaceuticals B.V., the Netherlands, $ 199,200, Jan.1, 2005 to Dec.31, 2006.

Evaluation of drug formulations for transdermal delivery, Undisclosed client, $ 64,800, Jan.1, 2005 to Dec.31, 2005.

Evaluation of acyclovir formulations in iontophoretic drug cartridges, Transport Pharmaceuticals (Framingham, MA), $ 21,000, Jan.1, 2005 to Dec.31, 2005.

Transdermal delivery of small molecules by thermal microporation, Altea Therapeutics (Atlanta, GA), $ 183,600, Jan. 1, 2005 to Dec. 31, 2006.

Transdermal delivery of proteins and peptides by thermal microporation, Altea Therapeutics (Atlanta, GA), $ 112,800, Jan. 1, 2005 to Dec. 31, 2006.

Delivery of NSAIDs into skin by iontophoresis and sampling by microdialysis, Travanti Pharma, Oakdale, MN, $ 25,200, October 18, 2004 to October 17, 2006.

Transdermal delivery of nicotine and its salts - issues and innovations, GlaxoSmithKline (Parsippany, NJ), $ 93,000, July 1, 2004 to June 30, 2005.

Delivery of proteins and peptides through the skin by the Altea Therapeutics PassPort System in animal models, Altea Therapeutics (Atlanta, GA), $ 127,200, Jan. 1, 2004 to Dec. 31, 2004.

Delivery of small molecule drugs through the skin by the Altea Therapeutics PassPort System in animal models, Altea Therapeutics (Atlanta, GA), $ 97,200, Jan. 1, 2004 to Dec. 31, 2004.

Iontophoretic transdermal delivery of nicotine salts, GlaxoSmithKline (Parsippany, NJ), $ 24,000, October 1, 2003 to March 31, 2004.

Skin permeation of nicotine, GlaxoSmithKline (Parsippany, NJ), $ 24,000, August 15, 2003 to February 14, 2004.

Delivery of parathyroid hormone through microporated skin, Altea Therapeutics (Atlanta, GA), $ 48,000, April 1, 2003 to March 31, 2004.

Modulated drug delivery through skin by iontophoresis and sampling by microdialysis, Birch Point Medical Inc., Oakdale, MN, $ 15,600, May 15, 2003 to May 14, 2004.

In vivo transdermal delivery of tetrahydrocannabinol formulations, Murty Pharmaceuticals, Inc., $ 8,400. Jan. 30, 2003 to Jan. 9, 2005.

Skin permeation studies of drug formulations, Solvay Pharmaceuticals, Inc., Marietta, GA, $ 26,400, Jan 2, 2003 to June 30, 2003.

Modulated transdermal drug delivery by iontophoresis, Birch Point Medical Inc., Oakdale, MN, $ 20,160, April 15, 2002 to April 14, 2003.

Drug solubilization by lipid vehicles, Lipocine Inc., Salt Lake City, UT, $ 5040, March 1, 2002 to August 30, 2002.

Enhanced insulin delivery by microporation and other active energy based flux enhancement, Altea Development Corporation, Atlanta, GA, $ 20,400, Jan.21, 2002 to Jan.20, 2003.

Enhanced in vivo transdermal drug delivery by iontophoresis, Birch Point Medical Inc., Oakdale, MN, $ 10,080, Jan.1, 2002 to Dec.31, 2002.

Enhanced *in vivo* transdermal drug delivery by microporation and other active energy based flux enhancement, Altea Development Corporation, Atlanta, GA, $ 178,680, July 1, 2001 to June 30, 2003.

Enhanced *in vitro* transdermal drug delivery by microporation and other active energy based flux enhancement, Altea Development Corporation, Atlanta, GA, $ 112,800, Jan.18, 2001 to Jan.17, 2003.

Transdermal delivery of tetrahydro-cannabinol, Murty Pharmaceuticals, Lexington, KY, $ 8,400. Dec.15, 2000 to Dec.15, 2002.

Delivery of pDNA and protein antigens through microporated skin, Altea Development Corp., Atlanta, GA, $ 228,420, November 1, 2000 to October 30, 2002. Principal Investigator. (Co-investigators: Drs Holbrook and Rothenberg).

Electrically modulated skin delivery of beta-blockers, National Institutes of Health, $ 140,002, August 1, 2000 to July 31, 2003.

Delivery of insulin through microporated skin, Altea Development Corp. (Atlanta, GA), $ 20,400, Aug. 10, 2000 to Aug.9, 2001.

Drug diffusion through Eudragit Films as a function of film composition, Elan Corporation (Gainesville, GA), $ 5040, 8/1/00-11/30/00. Formulation and delivery of interferon, Altea Development Corp. (Atlanta, GA), $ 20,400, July 5, 2000 to Jan.4, 2001.

Formulation of a plasticized gel for burn applications, Demegen, Inc. (Pittsburgh, PA), $ 20,400, Jan.15, 2000 to Jan.15, 2001.

Skin permeation studies for ibuprofen and flutamide, Aviana Biopharm (Wynnewood, PA), $ 4080, Jan.15, 2000 to Jan.15, 2001.

Electrically assisted delivery of fentanyl, Genetronics, Inc. (San Diego, CA), $ 4080, May'99 to Aug'99.

Electrically assisted delivery of parathyroid hormone, Genetronics, Inc. (San Diego, CA), $ 5040, March'99 to December'99.

Preparation and evaluation of a vaginal peptide gel, Demegen, Inc. (Pittsburgh, PA), $ 8,400, March' 99 to Feb' 2000.

Claim support study of salicylic acid body wash formulas, Blistex, Inc. (Oak Brook, IL), $ 8400. April'99 to July'99. Received another $ 2400 in May'99 to expand the project with more human subjects.

Electrically enhanced transdermal delivery of calcitonin, Small business innovation research grant, National Institute of Health thru Genetronics, Inc. (San Diego, CA), Aug' 97, $ 89,572 (direct costs). Author of grant, investigator for subcontract work and consultant.

Investigation of potential vaginal uptake of an anti-infective peptide, Demeter Biotechnologies, Ltd, Durham, NC, $ 15,000. January 1998 to August 1998.

Electroincorporation of buprenorphine microspheres in skin for treatment of opiate addiction, Genetronics Inc., San Diego, CA. $ 5,000. August 1997 to April 1998.

Gel formulation of nitroglycerin and transdermal delivery, $ 5,000. Seatrace Pharmaceuticals, Gadsden, AL.

Electrically-enhanced transdermal delivery of macromolecules, $ 3,800. School of Pharmacy Competitive Grant-in-Aid, March' 97.

Mechanism of release of potassium chloride from ethylcellulose and composite films, $ 10,000. Eurand America, Inc., a division of American Home Products, Dayton, Ohio. February' 97.

Electrically assisted transdermal delivery of colchicine from liposome formulations, Genetronics Inc., San Diego, CA. $ 2,200. February 1997. Electrically enhanced transdermal drug delivery of calcitonin, Genetronics Inc., San Diego, CA, $ 8,000. September 1996- March 1997.

Controlled release parenteral delivery system of buprenorphine, Small business innovation research award granted to Murty Pharmaceuticals, Inc by the National Institute of Health. $ 98,754. One of the Investigators in sub-contract work.

Electrically assisted transdermal drug delivery of prostaglandin E1, Genetronics Inc., San Diego, CA, $ 8,650. March 1996 to March 1997.

Electroincorporation of insulin microspheres in human skin, Genetronics Inc., San Diego, CA, $ 5,000. October 1995.

Emdex as a stabilizing excipient to prevent aggregation of peptide/protein drugs Mendell Drug Co., $ 20,000.

Electrically assisted delivery of Vasopressin through human skin, Auburn University Competitive Research Grant-in-Aid. Proposal was ranked #1 for funding on a university wide competitive basis. $ 10,000.

Use of Emu oil as a transdermal penetration enhancer, American Emu Association. $8,000 Co-Principal Investigator.

To investigate the role of excipients to prevent or minimize the aggregation of human growth hormone", School of Pharmacy Competitive Grant-in-aid. $ 3,500.

"Optimization of experimental conditions during transdermal iontophoresis studies, School of Pharmacy Competitive Grant-in-aid. $ 3,600.

Gift of chromatographic equipment from Lederle, a division of American Cyanamid Company, NY. The 12 pieces of used equipment gifted were valued by department (Pharmacal Sciences, Auburn University) at $ 40,000. Gift of human skin ($6000) and iontophoresis units ($ 1950) from Novartis Pharmaceuticals and HPLC analytical instrument ($ 15,000) from Bertek Labs to our laboratory at Mercer University.

BOOKS, PUBLICATIONS, AND PRESENTATIONS:

Books (both books are single author and not edited volumes)

Therapeutic Peptides and Proteins: Formulation, Processing, and Delivery Systems, Ajay K. Banga, Second Edition, 376pp., CRC Press/Taylor & Francis, 2005.

Electrically-assisted transdermal and topical drug delivery, Taylor & Francis, London, 1998.

Publications (*Corresponding author)

Application of Tzero calibrated modulated temperature differential scanning calorimetry to characterize model protein formulations, A. Badkar, P. Yohannes, and A. Banga, *International Journal of Pharmaceutics*, in press.

Iontophoretic Topical and Transdermal drug delivery, A. Banga, *Drug Delivery Companies Report*, Autumn/Winter 2005, PharmaVentures, UK.

Dermal, subdermal, and systemic concentrations of granisetron by iontophoretic delivery, A. Chaturvedula, D. P. Joshi, C. Anderson, R. Morris, W.L. Sembrowich, and A.K. Banga, *Pharmaceutical Research*, 22 (2005) 1313-1319.

In vivo iontophoretic delivery and pharmacokinetics of salmon calcitonin, A. Chaturvedula, D. P. Joshi, C. Anderson, R. Morris, W.L. Sembrowich, and A.K. Banga, *Int. J. Pharm.*, 297 (2005) 190-196.

Factorial design approach to evaluate interactions between electrically assisted enhancement and skin stripping for delivery of tacrine, A. C. Hirsch, R.S. Upasani, and A.K. Banga, *J.Control.Rel.*, 103 (1) (2005) 113-121.

Response surface methodology to investigate the iontophoretic delivery of tacrine hydrochloride, R.S. Upasani and A.K. Banga, *Pharmaceutical Research*, 21(12) (2004) 2293-2299.

Assessment of group projects beyond cooperative group effort, Ajay K. Banga, *Journal of Pharmacy Teaching*, 11(2) (2004): 115-123.

Iontophoretic *in vivo* transdermal delivery of beta-blockers in hairless rats and reduced skin irritation by liposomal formulation, R. Conjeevaram, A. Chaturvedula, G.V. Betageri, G. Sunkara, and A.K. Banga*, *Pharmaceutical Research*, 20 (9) (2003) 1496-1501.

Delivery of Protein Therapeutics, Ajay K. Banga, in: World Markets Series Business Briefing, Pharma Tech 2003, p.198-202.

Stability of a transdermal salmon calcitonin formulation, S.Chang, G.A. Hofmann, L. Zhang, L.J. Deftos, and A.K. Banga*, *Drug Delivery*, 10 (2003) 41-45.

Electrically modulated transdermal delivery of fentanyl, R. Conjeevaram, A.K. Banga*, and L. Zhang, *Pharm.Res.*., 19 (2002) 440-444.

Electrically enhanced transdermal delivery of a macromolecule, A.V. Badkar and A.K. Banga, J. Pharm. Pharmacol., 54 (2002) 907-912.

Drug delivery today, Ajay K. Banga, in: World Markets Series Business Briefing, Pharma Tech 2002, World Markets Research Centre Ltd., p.150-154.

Electrically assisted transdermal delivery of buprenorphine, Sagarika Bose, William R. Ravis, Yuh-Jing Lin, Lei Zhang, Gunter A. Hofmann, and Ajay K. Banga*, *J.Cont.Rel.*, 73 (2001) 197-203.

Transdermal iontophoretic drug delivery, Ajay K. Banga, in: World Markets Series Business Briefing, Pharma Tech 2001, World Markets Research Centre Ltd., p.203-204.

Use of intravaginal microbicides to prevent acquisition of Trichomonas vaginalis infection in Lactobacillus-pretreated, estrogenized young mice, W. B. Lushbaugh, A. C. Blossom, PH. Shah, A. K. Banga, J. M. Jaynes, J. D. Cleary, and R. W. Finley. *Am.J.Trop.Med.Hyg.* 63:284-289, 2000.

The effect of electroporation on iontophoretic transdermal delivery of calcium regulating hormones, Shu-Lun Chang, Gunter A. Hofmann, Lei Zhang, Leonard J. Deftos, and Ajay K. Banga*, *J.Cont.Rel.*, 66 (2000) 127-133.

Transdermal iontophoretic delivery of salmon calcitonin, Shu-Lun Chang, Gunter A. Hofmann, Lei Zhang, Leonard J. Deftos, and Ajay K. Banga*, *Int. J. Pharm.*, 200 (2000) 107-113.

In vitro release testing of a peptide gel, Advait Badkar, Kishore Talluri, Srini Tenjarla, Jesse Jaynes, and Ajay K. Banga*, Pharm.Technol., Jan.2000, pp.44-52

Innovations in drug delivery, Cynthia Starr (article consultants: Ajay K. Banga, Yie W. Chien, Richard G. Fischer, Douglas Goetz, and Robert Langer), Patient Care, Jan.15, 2000, pp.107-137.

Iontophoresis and Electroporation: Comparisons and Contrasts, Ajay K. Banga, Sagarika Bose and Tapash Ghosh, *International Journal of Pharmaceutics,* 179 (1999) 1-19.

Enhancement of transdermal iontophoretic delivery of a liposomal formulation of colchicine by electroporation, A.V. Badkar, G.V. Betageri, G.A. Hofmann, and A.K. Banga*, *Drug Delivery*, 6 (1999) 111-115.

Ajay K. Banga and Peter C. Panus, Clinical applications of iontophoretic devices in rehabilitation medicine, *Critical Reviews in Physical and Rehabilitation Medicine*, 10 (1998) 147-179.

Assessing the potential of skin electroporation for the delivery of protein- and gene-based drugs , Ajay K. Banga* and Mark R. Prausnitz, *Trends in Biotechnology, 16 (1998) 408-412.*

Transdermal iontophoretic delivery of hydrocortisone from cyclodextrin solutions, Shu-Lun Chang and Ajay K. Banga*, *J. Pharm.Pharmacol.*, 50 (1998) 635-640.

Controlled release of human growth hormone in rats following parenteral administration of poloxamer gels, Manohar Katakam, William R. Ravis and Ajay K. Banga*, *J.Cont.Rel.*, 49 (1997) 21-26.

Controlled release of human growth hormone following subcutaneous administration in dogs,Manohar Katakam, William R. Ravis, Dennis L. Golden and Ajay K. Banga*, *Int. J. Pharm.*, 152 (1997) 53-58.

Use of poloxamer polymers to stabilize recombinant human growth hormone against various processing stresses, Manohar Katakam and Ajay K. Banga*, *Pharm.Dev.Technol., 2 (1997) 143-149.*

Transdermal iontophoretic delivery of ketoprofen through human cadaver skin and in humans, Peter C. Panus, Jennifer Campbell, Shirishkumar B. Kulkarni, Richard T. Herrick, William R. Ravis, and Ajay K. Banga*, *J.Control.Rel., 44 (1997) 113-121.*

Liposomal formulation and characterization of the opioid leucine enkephalin, Guru V. Betageri, Narendra B. Vutla, and Ajay K. Banga*, *Pharm.Sci.*, 3 (1997) 587-591.

Iontophoresis devices and clinical applications for topical delivery,Peter Panus and Ajay K. Banga*, *Int.J.Pharm.Comp.*, 1 (1997) 420-424.

Effect of iontophoretic current and application time on transdermal delivery of ketoprofen in man, Peter C. Panus, Shirishkumar B. Kulkarni, Jennifer Campbell, William R. Ravis, and Ajay K. Banga*, *Pharm.Sci.*, 2 (1996) 467-469.

Transdermal iontophoretic delivery of colchicine encapsulated in liposomes, Shirishkumar B. Kulkarni, Ajay K. Banga, and Guru V. Betageri, *Drug Delivery, 3 (1996) 245-250.*

Transdermal iontophoretic delivery of enkephalin formulated in liposomes, Narendra B. Vutla, Guru V. Betageri, and Ajay K. Banga*, *J.Pharm.Sci.*, 85 (1996) 5-8.

Selection of electrode material and polarity in the design of iontophoresis experiments, Ajay K. Banga*, Shirishkumar Kulkarni, and Ruchira Mitra, *Int.J.Pharm.Adv., 1 (1995) 206-215.*

Aggregation of Insulin and its prevention by carbohydrate excipients, Manohar Katakam and Ajay K. Banga*, *PDA J.Pharm.Sci.Technol.*,49 (1995) 160-165

Effect of surfactants on the physical stability of recombinant human growth hormone, Manohar Katakam, Leonard N. Bell and Ajay K. Banga*, *J. Pharm. Sci.*, 84 (1995) 713-716.

Transdermal iontophoretic delivery and degradation of vasopressin across human cadaver skin, Ajay K. Banga*, Manohar Katakam and Ruchira Mitra, *Int. J. Pharm.*, 116 (1995) 211-216.

Aggregation of Proteins and its prevention by carbohydrate excipients: Albumins and γ-globulin, Manohar Katakam and Ajay K. Banga*, *J.Pharm.Pharmacol.*, 47 (1995) 103-107.

Iontophoresis and Phonophoresis, Robin H. Bogner and Ajay K. Banga, *U.S. Pharmacist*, pp.H-10 to H-26, August 1994.

Biotechnology Drugs: Pharmaceutical issues, Ajay K. Banga and Indra K. Reddy, *Pharmacy Times*, March 1994 (also published in the *J. Practical Nursing*, March 1996).

Minimization of shaking-induced formation of insoluble aggregates of insulin by cyclodextrins, Ajay K. Banga* and Ruchira Mitra, *J. Drug Target.*, 1 (1993) 341-345.

Biotechnology Drugs: Oral Vs Alternate Routes, Indra K. Reddy and Ajay K. Banga, *Pharmacy Times*, November 1993.

Hydrogel-based iontotherapeutic delivery devices for transdermal delivery of peptide/protein drugs, Ajay K. Banga and Yie W. Chien, *Pharm. Res.*, 10 (1993) 697-702.

Methods of enhancement of transdermal drug delivery: Part I: Physical and Biochemical Approaches, Tapash Ghosh and Ajay K. Banga, *Pharm. Technol.*, March 1993.

Methods of enhancement of transdermal drug delivery: Part IIA: Chemical permeation enhancers, Tapash Ghosh and Ajay K. Banga, *Pharm. Technol.*, *April 1993.*

Methods of enhancement of transdermal drug delivery: Part IIB: Chemical permeation enhancers, Tapash Ghosh and Ajay K. Banga, *Pharm. Technol.*, *May 1993.*

Characterization of in-vitro transdermal iontophoretic delivery of insulin, Ajay K. Banga and Yie W. Chien, *Drug Dev. Ind. Pharm.*, 19 (1993) 2069-2087.

Cessione transdermica di insulina con metodo ionoforetico (Transdermal iontophoretic delivery of insulin), Ajay K. Banga and Yie W. Chien, *MEDICO & diabete*, anno 4-n.42-43. agosto/settembre 1992.

Potential developments in systemic delivery of insulin, Yie W. Chien and Ajay K. Banga, *Drug Dev. Ind. Pharm.*, 15 (1989) 1601-1634.

Iontophoretic (Transdermal) delivery of drugs: Overview of historical development, Yie W. Chien and Ajay K. Banga, *J. Pharm. Sci.*, 78 (1989) 353.

Incorporation of simethicone into syrupy or clear base liquid orals, Ajay K. Banga, Loyd V. Allen, Robert B. Greenwood, M. Lou Stiles and Willis L. Owen, *Drug Dev. Ind. Pharm.*, 15 (1989) 691-704.

Iontophoretic delivery of drugs: Fundamentals, developments and biomedical applications, Ajay K. Banga and Yie W. Chien, *J. Control. Rel.*, 7 (1988) 1-24.

Systemic delivery of therapeutic peptides and proteins, Ajay K. Banga and Yie W. Chien, *Int. J. Pharmaceutics*, 48 (1988) 15-50.

Investigations on a new coating technique based on sedimentation of core material through a multiphase system, A.K. Banga and A.K. Madan, *The East. Pharm.*, 27 (1984) 139-145.

Book Chapters and Patents

Electrically-assisted transdermal delivery of drugs, Ajay K. Banga, Chapter 27, in: *Handbook of Pharmaceutical Controlled Release Technology*, Marcel Dekker, Inc., NY, 2000, p.567-581.

Protein and peptide drug delivery to the eye, Ajay K. Banga, Chapter 16, p.461-487, in: *Ocular Therapeutics and Drug Delivery: A Multi-disciplinary approach*, Ed. Indra K. Reddy, Technomic,

1996.Peptide and protein drug delivery, Lorraine Wearley and Ajay K. Banga, in: *Encyclopedia of Pharmaceutical Technology*, Eds J. Swarbrick and J.C. Boylan, Vol.11, pp.395-411, Marcel Dekker, Inc., 1995.

Dermal absorption of peptides and proteins, Ajay K. Banga and Yie W. Chien, Chapter 8, p.179-197, in: *Pharmaceutical Biotechnology, Vol. 4: Biological barriers to protein delivery*, Eds Kenneth L. Audus and Thomas Raub, Series Editor, Ronald T. Borchardt, Plenum press, 1993.

Iontotherapeutic devices, reservoir electrode devices therefore, process and unit dose, Yie W. Chien and Ajay K. Banga, U.S. Patent No. 5,250,022 dated Oct.5, 1993 (this patent was licensed by Sintong Corporation on May 17, 1994).

A process for coating based on passage of cold core material through multiphase system, Ajay K. Banga, Anil K. Madan and Bhagwan D. Miglani, *Patent # 158678,* dated May 11, 1983, Patent Office, Govt. of India.

Presentations at Scientific Meetings

C. Wang, P. Pendse, R. Durland, and A. Banga, Microporation: Needle-free transdermal vaccination using BSA as model antigen in mice, presented at the Georgia Life Sciences Summit, Georgia World Congress Center, Atlanta, October 27, 2005.

R. Upasani, Y. Yang, and A. Banga, Mapping the influence of ionization state of nicotine and ionic surfactants on the iontophoretic transport of nicotine using response surfaces, presented at the 32nd annual meeting of the Controlled release society, June 18-22, 2005, Miami Beach, FL.

G. Tolia, S. Chang, H. Branam, S. Mills, S. Desai, C. Kolli, and A. Banga, Transdermal delivery of hydromorphone in hairless rats by thermal microporation, presented at the 32nd annual meeting of the Controlled release society, June 18-22, 2005, Miami Beach, FL.

S. Late and A. Banga, Differential scanning calorimetry as a screening technique to assess the compatibility of granisetron hydrochloride with commonly used tablet excipients, 25th annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Long Island University, NY, June 10-12, 2005.

A. Badkar and A. Banga, Effects of various stress factors on aggregation of concentrated immunoglobulin G formulations, presented at the AAPS annual meeting, October 2004, Baltimore, MD.

R. Upasani, A. Hirsch, and A. Banga, Evaluation of effects of iontophoresis, electroporation and skin stripping on the percutaneous penetration of tacrine hydrochloride using factorial design, presented at the AAPS annual meeting, October 2004, Baltimore, MD.

P. Pendse, R. Bright, R. Durland, C. Wang, and A. Banga, Thermal microporation as a novel technique for transdermal immunization with model antigens, presented at the AAPS annual meeting, October 2004, Baltimore, MD.

A. Chaturvedula, D. Joshi, C. Anderson, R. Morris, and A. Banga, IVIVC of iontophoretic delivery of granisetron by subcutaneous microdialysis, presented at the AAPS annual meeting, October 2004, Baltimore, MD.

A. Badkar and A. Banga, Effects of formulation pH and buffers on thermal properties and conformational stability of Immunoglobulin G, 24th annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004.

P. Pendse, R. Bright, R. Durland, C. Wang, and A.K. Banga, Thermal microporation as a novel technique for transdermal immunization with model antigens, 24th annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004.

R. Upasani, A. Hirsch, and A. Banga, Evaluation of effects of iontophoresis, electroporation and skin stripping on the percutaneous penetration of tacrine hydrochloride using factorial design, 24th annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004.

A. Chaturvedula, D.P. Joshi, C. Anderson, R. Morris, W. Sembrowich, and A. Banga, Evaluation of in vivo iontophoretic delivery of salmon calcitonin, presented at the 31st annual meeting of the Controlled release society, June 12-16, 2004, Honolulu, Hawaii, USA, and at the 24th annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004.

A. Chaturvedula, A.M. Smith, and A. K. Banga, Delivery of opioid analgesics through micropores in the skin,, presented at the 2003 Annual Meeting of the American Association of Pharmaceutical Scientists, October 26-30, 2003, Salt Lake City, Utah.

R.S. Upasani and A. K. Banga, Response surface modeling to optimize the iontophoretic delivery of tacrine HCl, presented at the 2003 Annual Meeting of the American Association of Pharmaceutical Scientists, October 26-30, 2003, Salt Lake City, Utah.

A. Chaturvedula, C. Anderson, R. Morris, and A. K. Banga, Evaluation of stereoselective iontophoretic permeation kinetics of propranolol through skin by subcutaneous microdialysis, presented at the 2003 Annual Meeting of the American Association of Pharmaceutical Scientists, October 26-30, 2003, Salt Lake City, Utah.

D.P. Joshi, A. Chaturvedula, S.L. Chang, S.E. Mills, A.M. Smith, and A. K. Banga, Steady insulin infusion via micropores through the stratum corneum in hairless rats, presented at the 2003 Annual Meeting of the American Association of Pharmaceutical Scientists, October 26-30, 2003, Salt Lake City, Utah.

A.V. Badkar, P. Yohannes, and A. K. Banga, Effect of formulation on thermal properties of lysozyme: Characterization by modulated DSC, presented at the 2003 Annual Meeting of the American Association of Pharmaceutical Scientists, October 26-30, 2003, Salt Lake City, Utah.

A. Chaturvedula, D.P. Joshi, C. Anderson, R. Morris, and A. K. Banga, Evaluation of iontophoretic permeation kinetics of granisetron through skin by subcutaneous microdialysis, presented at the 2003 Annual Meeting of the American Association of Pharmaceutical Scientists, October 26-30, 2003, Salt Lake City, Utah.

A.V. Badkar, A.M. Smith, J.A. Eppstein, and A. K. Banga, Delivery of interferon alpha 2b through micropores in the stratum corneum by passive diffusion and electrotransport in hairless rats, presented at the 2003 Annual Meeting of the American Association of Pharmaceutical Scientists, October 26-30, 2003, Salt Lake City, Utah.

A. Chaturvedula, R. Conjeevaram, C. Anderson, R. Morris, and A. Banga, Transdermal delivery of propranolol HCl to hairless rats using a self-contained iontophoretic patch, presented at the 30th annual meeting of the Controlled release society in Glasgow, Scotland, July 19-23, 2003 and the annual meeting of graduate research association of students in pharmaceutics conference, Richmond, VA, May 30-June 1, 2003.

A. Badkar, P. Yohannes, and A.K. Banga, Thermal characterization of protein formulation using modulated temperature differential scanning calorimetry, presented at the Annual meeting of the Georgia Academy of Sciences, March 21-22, 2003.

R.V. Conjeevaram, A. Chaturvedula, G.V. Betageri, and A. K. Banga, In vivo transdermal delivery of beta blockers in hairless rats, presented at the 2002 Annual Meeting of the American Association of Pharmaceutical Scientists, November 10-14, 2002, Toronto, Canada.

R.V. Conjeevaram, V. Michaud, A.V. Badkar, G.V. Betageri, and A. K. Banga, Delivery of propranolol liposomes across hairless rat skin, presented at the 2002 Annual Meeting of the American Association of Pharmaceutical Scientists, November 10-14, 2002, Toronto, Canada.

A.V. Badkar, A.M. Smith, J.A. Eppstein, and A. K. Banga, Low frequency, pulse-modulated ultrasound-mediated delivery of interferon alpha 2b through thermally created micropores across hairless mouse skin - A mechanistic study, presented at the 2002 Annual Meeting of the American Association of Pharmaceutical Scientists, November 10-14, 2002, Toronto, Canada, and at the 22nd annual meeting of graduate research association of students in pharmaceutics conference, University of Georgia, Athens, Georgia, May 24-26, 2002.

A. Badkar, A. Smith, J. Eppstein, and A. Banga, Transdermal delivery of interferon alpha-2b in hairless rats by thermal microporation , presented at IBC's 2nd International Conference on "Protein and peptide drug delivery : Scientific advances enabling novel approaches and improved products", Sept.26-27, 2002, Boston, MA.

A. Banga, Assessment of group projects beyond cooperative group effort, presented at the annual meeting of American Association of Colleges of Pharmacy (AACP), Kansas City, July 16, 2002.

A. Badkar, A. Smith, J. Eppstein, and A. Banga, Pulsatile delivery of nicotine across hairless rat skin, presented at the 22nd annual meeting of graduate research association of students in pharmaceutics conference, University of Georgia, Athens, Georgia, May 24-26, 2002.

R. Conjeevaram, G. Betageri, and A. K. Banga, Electrically modulated skin delivery of beta blockers, presented at the 2001 Annual Meeting of the American Association of Pharmaceutical Scientists, October 21-25, 2001, Denver, Colorado.

D.P. Joshi, R. Conjeevaram, S. Palaniswamy, G.S. Rekhi, and A. K. Banga, To study the effect of polymer film composition on permeability of water soluble drug using diffusion cells, presented at the 2001 Annual Meeting of the American Association of Pharmaceutical Scientists, October 21-25, 2001, Denver, Colorado.

S. Chang, A.M. Smith, S.E. Mills, D.P. Joshi, A.V. Badkar, and A.K. Banga, Transdermal delivery of human parathyroid hormone 1-34 by thermally created micropores and electrotransport,, presented at the 2001 Annual Meeting of the American Association of Pharmaceutical Scientists, October 21-25, 2001, Denver, Colorado.

A.V. Badkar and A. K. Banga, In vitro release testing of a non-aqueous gel, presented at the 2001 Annual Meeting of the American Association of Pharmaceutical Scientists, October 21-25, 2001, Denver, Colorado.

A.V. Badkar, A.M. Smith, J.A. Eppstein, and A.K. Banga, Delivery of interferon alpha-2b through thermally created micropores in hairless mouse skin by passive diffusion and electrical enhancement techniques,, presented at the 2001 Annual Meeting of the American Association of Pharmaceutical Scientists, October 21-25, 2001, Denver, Colorado.

R. Conjeevaram, L. Zhang, and A. Banga, Electrically assisted delivery of fentanyl, presented at the 28th International Symposium on Controlled Release of Bioactive Materials, June 23-27, 2001, San Diego, California, and at the 21st annual meeting of graduate research association of students in pharmaceutics conference, June 8-10, 2001, University of Connecticut, Storrs, Connecticut.

A. Smith, A. Badkar, J. Eppstein, S. Chang, S. Mills, and A. Banga, Delivery of interferon alpha-2b through thermally created micropores in hairless mouse skin by passive diffusion and pulse-modulated low frequency ultrasound, presented at the 28th International Symposium on Controlled Release of Bioactive Materials, June 23-27, 2001, San Diego, California.

D.P. Joshi, A.M. Smith, J.A. Eppstein, and A.K. Banga, Transdermal delivery of insulin across hairless mouse skin: Studying the effects of various enhancement techniques, presented at the 21st annual meeting of graduate research association of students in pharmaceutics conference, June 8-10, 2001, University of Connecticut, Storrs, Connecticut.

A. Badkar, A. Smith, J. Eppstein, and A. Banga, Delivery of interferon alpha-2b through thermally created micropores in hairless mouse skin by passive diffusion and electrical enhancement techniques, presented at the 21st annual meeting of graduate research association of students in pharmaceutics conference, June 8-10, 2001, University of Connecticut, Storrs, Connecticut.

L. Zhang, K. Azadzoi, S.L. Chang, A.K. Banga, G.A. Hofmann, D.P. Rabussay, and I. Goldstein, Potential non-invasive approach to ameliorate male erectile dysfunction by electroporation: Feasibility evaluation in vitro across human skin, animal

model and human subjects, to be presented at the 9th world meeting of the International Society for Impotence Research, Nov. 26-30, 2000, Perth, Western Australia.

Rajkumar Conjeevaram and Ajay K. Banga, Transdermal iontophoretic delivery of timolol, presented at the 2000 Annual Meeting of the American Association of Pharmaceutical Scientists, October 29 - November 2, 2000, Indianapolis, Indiana.

Rajkumar Conjeevaram and Ajay K. Banga, Transdermal iontophoretic delivery of timolol, presented at the 20th annual meeting of graduate research association of students in pharmaceutics conference, June 2-4, 2000, University of Maryland, Baltimore, Maryland.

Advait Badkar and Ajay K. Banga, *In Vitro* release testing of a non-aqueous gel, presented at the 20th annual meeting of graduate research association of students in pharmaceutics conference, June 2-4, 2000, University of Maryland, Baltimore, Maryland.

Rajkumar Conjeevaram and Ajay K. Banga, Transdermal iontophoretic delivery of timolol, presented at the Mercer Univesity Health Sciences Research Conference, April 27, 2000, Macon, Georgia.

L.Zhang, G.A. Hofmann, S. Bleecher, N.B.Dev, L.Deftos, S.L.Chang, and A.K. Banga, Synergy of transdermal delivery of therapeutics by electrically assisted methods, presented at the Asian Conference and Exhibition of Controlled Release, November 29-December 1, 1999, Hong Kong, China.

W.B. Lushbaugh, A. Paxton, P. Shah, A. Banga, J. Jaynes, J. Cleary, and R. Finley, Intravaginal microbicides prevent acquisition of trichomonas vaginalis infection in a mouse model, presented at the 48th annual meeting of the American Society of Tropical Medicine and Hygiene, November 28, 1999, Washington D.C.

K. Talluri, A. Badkar, S. Tenjarla and A. Banga, In vitro release testing of a peptide gel, presented at the *1999 annual meeting of the American Association of Pharmaceutical Scientists, November 14-18, 1999, New Orleans, LA.*

S. Chang, G. Hofmann, L. Zhang, L. Deftos, and A. Banga, Skin transport and stability of calcitonin under electric field, presented at the *1999 annual meeting of the American Association of Pharmaceutical Scientists, November 14-18, 1999, New Orleans, LA.*

Shu-Lun Chang, Gunter A. Hofmann, Lei Zhang and Ajay K. Banga, Skin transport of calcitonin by Electroporation and stability under electric field, presented at the *19th Annual Meeting of GRASP,Holiday Inn, Columbia, SC (Host: University of South Carolina & Medical University of South Carolina), May 28-30, 1999.*

Kishore Talluri, Advait Badkar, Srini Tenjarla, and Ajay K. Banga, In Vitro release testing on a peptide gel as per SUPAC-SS recommendations, presented at the *19th Annual Meeting of GRASP,Holiday Inn, Columbia, SC (Host: University of South Carolina & Medical University of South Carolina), May 28-30, 1999.*

Sagarika Bose, Yuh-Jing Lin, William R. Ravis, Günter A. Hofmann, and Ajay K. Banga, Transdermal delivery of buprenorphine microspheres by embedding particles in human skin, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Sagarika Bose, William R. Ravis, Gunter A. Hofmann, and Ajay K. Banga, Effect of electroporation on transdermal iontophoretic delivery of buprenorphine, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Shu-Lun Chang, Günter A. Hofmann, Lei Zhang and Ajay K. Banga, Electrically assisted transdermal delivery of a salmon calcitonin formulation, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Advait Badkar, Günter A. Hofmann, Guru Betageri and Ajay K. Banga, Enhancement of transdermal iontophoretic delivery of a liposomal colchicine formulation by electroporation, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Advait V. Badkar and Ajay K. Banga, Enhancement of transdermal iontophoretic delivery of dextran sulfate by electroporation across full-thickness pig skin, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Advait V. Badkar and Ajay K. Banga, Electrically assisted transdermal delivery of a macromolecule across human skin, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Shu-Lun Chang, Ajay K. Banga, Günter A. Hofmann and Lei Zhang, Transdermal delivery of prostaglandin e1 by embedding particles in human penile skin, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Rajkumar Conjeevaram, Guru V. Betageri and Ajay K. Banga, Transdermal delivery of propranolol solution and liposmal formulation by iontophoresis and electroporation, presented at the *1998 annual meeting of the American Association of Pharmaceutical Scientists, November 15-19, San Francisco, CA.*

Sagarika Bose, William R. Ravis, Gunter A. Hofmann, and Ajay K. Banga, Electrically-assisted Transdermal Delivery of Buprenorphine, presented at the *18th Annual Meeting of GRASP, Holiday Inn-Select, Clark, NJ (Host: Rutgers University), May 29-31, 1998.*

Shu-Lun Chang, Gunter A. Hofmann, Lei Zhang and Ajay K. Banga, Stability of Salmon Calcitonin Formulation and Enhancement of its Transdermal Iontophoretic Delivery by Electroporation, presented at the *18th Annual Meeting of GRASP,Holiday Inn-Select, Clark, NJ (Host: Rutgers University),May 29-31, 1998.*

Advait V. Badkar and Ajay K. Banga, Enhancement of Transdermal Iontophoretic Delivery of a Macromolecule by Electroporation, presented at the *18th Annual Meeting of GRASP, Holiday Inn-Select, Clark, NJ (Host: Rutgers University), May 29-31, 1998.*

Ajay K. Banga, , Shirishkumar B. Kulkarni, Jennifer Campbell, Richard T. Herrick, William Ravis, and Peter C. Panus, Iontophoretic delivery of ketoprofen to healthy volunteers as a function of current and time, presented at the annual meeting of *American Association of Pharmaceutical Scientists, Seattle, October 27-31, 1996.*

Shu-Lun Chang and Ajay K. Banga, Iontophoretic delivery of hydrocortisone from cyclodextrin solutions, presented at the annual meeting of *American Association of Pharmaceutical Scientists, Seattle, October 27-31, 1996.*

Manohar Katakam, and Ajay K. Banga, Use of poloxamer polymers to stabilize recombinant human growth hormone against various processing stress, presented at the annual meeting of *American Association of Pharmaceutical Scientists, Seattle, October 27-31, 1996.*

Manohar Katakam, William R. Ravis, Dennis L. Golden, and Ajay K. Banga,Controlled release of human growth hormone following subcutaneous administration in dogs, presented at the annual meeting of *American Association of Pharmaceutical Scientists, Seattle, October 27-31, 1996.*

Manohar Katakam, William R. Ravis, and Ajay K. Banga,Controlled release of human growth hormone from poloxamer gels injected in rats, presented at the annual meeting of *American Association of Pharmaceutical Scientists, Seattle, October 27-31, 1996.*

S.B. Kulkarni, A.K. Banga, and G.V. Betageri, Delivery of liposome encapsulated colchicine across human cadaver skin using iontophoresis, presented at the annual meeting of *American Association of Pharmaceutical Scientists, Seattle, October 27-31, 1996.*

Faculty Mentor Group, Reflections on a Pilot Faculty-Mentor Team Experience, presented at the annual meeting of the American Association of Colleges of Pharmacy, Reno, Nevada, July 14-18, 1996.

Faculty Mentor Group, The Auburn University school of pharmacy orientation program: An authentic experience, presented at the annual meeting of the American Association of Colleges of Pharmacy, Reno, Nevada, July 14-18, 1996.

Peter C. Panus, Jennifer Campbell, Shirishkumar B. Kulkarni, Richard T. Herrick, William R. Ravis, and Ajay K. Banga Transdermal iontophoretic delivery of ketoprofen through human cadaver skin and in humans, presented at the annual meeting of the American Physical Therapists Association, Minneapolis, Minnesota, June 16, 1996 (abstract published Physical Therapy, v.76, no.5, May 1996, p.S67-68).

Manohar Katakam, Leonard N. Bell, and Ajay K. Banga, Physical stability of recombinant human growth hormone, presented at the annual meeting of *American Association of Pharmaceutical Scientists, November 5-9, 1995, Miami Beach, FL.*

Peter C. Panus, Jennifer Campbell, Shirishkumar B. Kulkarni, Richard T. Herrick, William Ravis, and Ajay K. Banga, Iontophoretic delivery of ketoprofen to healthy volunteers, presented at the annual meeting of *American Association of Pharmaceutical Scientists, November 5-9, 1995, Miami Beach, FL.*

Jennifer D. Campbell, Shirishkumar B. Kulkarni, Peter C. Panus, Richard T. Herrick, William R. Ravis, and Ajay K. Banga, *15th Annual Meeting of GRASP,St. John's University, Jamaica, NY, June 2-4, 1995.*

Manohar Katakam, Leonard N. Bell, and Ajay K. Banga, Role of nonionic surfactants on the stability of recombinant human growth hormone, *15th Annual Meeting of GRASP, St. John's University, Jamaica, NY, June 2-4, 1995 (this paper won the best poster award at the meeting).*

Narendra B. Vutla, Guru V. Betageri, and Ajay K. Banga, Encapsulation of Leucine Enkephalin in multilamellar and large unilamellar liposomes, *15th Annual Meeting of GRASP, St. John's University, Jamaica, NY, June 2-4, 1995.*

Transdermal iontophoretic delivery and degradation of vasopressin across human cadaver skin, Ajay K. Banga, Manohar Katakam and Ruchira Mitra, *AAPS Annual Meeting, San Diego, November 6-10, 1994.*

Aggregation of Insulin and its prevention by carbohydrate excipients, Manohar Katakam and Ajay K. Banga, *AAPS Annual Meeting, San Diego, November 6-10, 1994.*

Transdermal iontophoretic delivery of peptide/protein drugs, Ajay K. Banga and Ruchira Mitra, 71st annual meeting of the *Alabama Academy of Sciences, Troy State University, Troy, AL, March 24, 1994*

Aggregation of proteins and its prevention by carbohydrate excipients, Manohar Katakam and Ajay K. Banga, 71st annual meeting of the *Alabama Academy of Sciences, Troy State University, Troy, AL, March 24, 1994*

Transdermal iontophoretic transport of an aromatic amino acid and the effect of cyclodextrins on such transport, Ajay K. Banga, Daniel L. Parsons and Manohar Katakam, *AAPS Annual Meeting, Orlando, Nov. 1993.*

Aggregation of albumins and gamma globulin in the solid state and its prevention by excipients, Manohar Katakam and Ajay K. Banga, *AAPS Annual Meeting, Orlando, Nov.1993.*

Insulin aggregation and its prevention by cyclodextrins, Ajay K. Banga and Ruchira Mitra, *AAPS Annual Meeting, San Antonio, Nov.15-19, 1992.*

Hydrogels for iontophoretic delivery of peptide drugs, Ajay K. Banga and Yie W. Chien, *World Technology Exchange meeting*, Bausch & Lomb, Rochester, NY, 1991.

Transdermal iontophoretic delivery of peptide drugs: delivery mechanisms and hydrogel formulations, Ajay K. Banga and Yie W. Chien, *AAPS Annual meeting, Las Vegas, Nevada, Nov. 4-8, 1990.*

Iontophoretic transdermal delivery of insulin: I. Characterization of in-vitro permeation profiles, Ajay K. Banga and Yie W. Chien, *AAPS Annual Meeting, Atlanta, Georgia, Oct. 22-26, 1989.*

Iontophoretic transdermal delivery of insulin: II. Factors influencing in-vitro profiles, Ajay K. Banga and Yie W. Chien, *AAPS Annual Meeting, Atlanta, Georgia, Oct. 22-26, 1989.*

The incorporation of simethicone into clear base liquid orals, Ajay K. Banga, Loyd V. Allen et al., *Joint Japan-United States Congress of Pharmaceutical Sciences, Honolulu, Hawaii, Dec.2-7, 1987.*

INDUSTRIAL EXPERIENCE

Formulation Scientist at Bausch & Lomb, Rochester, NY. Responsible for formulation development and pilot plant scale up for sterile dosage forms. Manufactured several pilot batches and clinical supplies under GMP conditions. Started a new formulation laboratory, including sourcing and purchase of laboratory instrumentation.

Research Scientist at Ranbaxy Labs Ltd, the largest pharmaceutical company in India, and with business extending to more than 50 countries worldwide, including collaboration with Bausch & Lomb and a major global alliance with Eli Lilly and Company. Responsibilities included research on controlled release dosage forms and formulation development in conventional solid (tablets, capsules and dry syrups) and liquid (syrups and suspensions) dosage forms. Worked on preformulation studies, product development bench work, stability studies, pilot plant scale up and technology transfer to production floor.

INVITED LECTURES/WORKSHOPS CONDUCTED

Formulation and delivery of peptide/protein drugs, invited lecture at National Institute of Technology and Management, Lucknow, India and Matrix Laboratories, Hyderabad, India, December 2005.

Enhancement technologies for transdermal delivery, invited lecture at the Food and Drug Administration, June 2, 2005, Silver Springs, MD.

Enhancement methods for transdermal drug delivery, invited lecture at Georgia Institute of Technology, Atlanta, GA, April 26, 2005.

Coordinated a discussion on "Education in Pharmaceutical Sciences" at the Georgia Institute of Technology, Atlanta, GA, April 26, 2005.

Formulation of protein drugs and Enhanced transdermal delivery, lectures (total 6 hrs) in drug delivery graduate course at School of Pharmacy, Florida A&M University, Tallahassee, FL, April 5, 2004.

Transdermal drug delivery: Present & future directions, invited CE lecture, Mercer University, Atlanta, GA, Nov.11, 2003.

Protein formulation and delivery, invited lecture at Altea Therapeutics, Atlanta, GA, Nov.22, 2002.

Approaches to enhanced/modulated drug delivery through skin, invited lecture at Solvay Pharmaceuticals, Marietta, GA, June 13, 2002.

Transdermal modulated drug delivery, presentation to the Deans Board of Visitors, Mercer University School of Pharmacy, May 15, 2002.

Skin Delivery of Macromolecules, invited lecture at the 53rd Indian Pharmaceutical Congress and the Center for Biomedical Engineering at the Indian Institute of Technology in New Delhi, Dec.20-23, 2001.

Transdermal delivery of macromolecules, invited lecture at the Seminar program of University of Georgia College of Pharmacy, Athens, GA, Jan. 11, 2001.

Delivery systems and formulation considerations for peptide/protein drugs, a full-day lecture in a drug delivery graduate course at Florida A & M University, Tallahassee, Florida, May 3, 2000.

Organized a short course on "Protein and Gene-based Drugs: Product Development and Delivery Challenges" at the 1999 annual meeting of the American Association of Pharmaceutical Scientists, November 14-18, 1999, New Orleans, LA. Also, gave the opening lecture at this course, "Challenges in the product development and delivery of protein-based drugs."

Electrically-assisted transdermal delivery of peptides, invited lecture at the 19th Annual Meeting of GRASP (Grad. Res. Assoc. Students Pharmaceutics), Holiday Inn, Columbia, SC, May 29-30, 1999.

Electrically assisted transdermal and topical drug delivery, presentation to the seminar program at the School of Medicine, University of Alabama at Birmingham, AL, February 3, 1999.

Applications of physics in the design of novel drug delivery systems, lecture to undergraduate physics class, Auburn University, AL, January 15, 1999.

Organized (as one of the speakers) a 2-day, 3-speaker seminar on "Product Development of Therapeutic Peptides and Proteins", Logan Airport Ramada, Boston, MA, June 11-12, 1998.

Formulation of antimicrobial peptides as gels for Vaginal Use, presentation at Pre-Clinical Topical Microbicides Workshop, National Institute of Allergy and Infectious Diseases, Embassy Suites Hotel Buckhead, Atlanta, GA, May 20-21, 1998 (invited for presentation by NIH).

Characterization and formulation of recombinant proteins, presentation followed by consulting for Procter & Gamble Co., Cincinnati, Ohio, May 5, 1998.

Formulation & Delivery of Therapeutic Peptides and Proteins, presentation given to Eli Lilly & Co. World Headquarters, Indianapolis, IN, November 21, 1997.

Organized (as one of the speakers) a 3-day, 3-speaker seminar on "Peptides and Proteins as Parenteral Dosage Forms: Practical Issues in Formulation", Hotel International, Basel, Switzerland, May 21-23, 1997.

Electrically enhanced transdermal delivery of drugs, presentation given to Empi, Inc., St. Paul, Minnesota, February 17, 1997.

Formulation development of peptide drugs, presentation given to Demeter Biotechnologies, Ltd., Durham, NC, October 24, 1996 (Host: Vice President, Product Development).

Organized and conducted (as one of the speakers) a 2-day, 2-speaker seminar on "Iontophoretic Transdermal Drug Delivery: A New Commercially Feasible Technology ", Hotel International, Basel, Switzerland, October 17-18, 1996.

Electrically enhanced transdermal delivery of drugs, presentation given to Apollon, Inc., Malvern, Pennsylvania, October 11, 1996.

Formulation and Delivery of Therapeutic Peptides and Proteins, presentation given to Eurand America, Inc., a division of American Home Products, Dayton, Ohio, September 17, 1996.

Organized and conducted (as one of the speakers) a 2-day, 2-speaker seminar on "Therapeutic Peptides and Proteins: Practical Issues in Formulation Development", Hotel International, Basel, Switzerland, April 11-12, 1996.

Formulation of Therapeutic Proteins, Pharmaceutical Development, Ciba-Geigy World Headquarters, Basel, Switzerland, April 10, 1996 (Host: Dr. Tudor Arvinte, Head of Exploratory Formulation Development Laboratory).

Formulation and Delivery of Therapeutic Peptides and Proteins, Department of Pharmacy, King's College London, University of London, London, December 11, 1995 (Host: Dr. Gary P. Martin, Reader in Pharmaceutics).

Organized and conducted (as one of the speakers) a 2-day, 2-speaker seminar on "Therapeutic Peptides and Proteins: Practical Issues in Formulation Development", Sheraton Harbor Island Resort, September 28-29, 1995, San Diego, CA.

Transdermal iontophoretic delivery of drugs, Genetronics Inc., San Diego, CA, September 27, 1995, (Host: Dr.Gunter Hofmann, Founder, Chairman, and Chief Scientific Officer).

Conducted a Workshop on "Pharmaceutical Issues of Biotechnology Drugs" for the faculty of St. John's University, March 16, 1994, New York (Host: Faculty Development Committee).

Formulation and delivery of peptide/protein drugs, Ranbaxy Laboratories Ltd., New Delhi, India, January 3, 1994 (Host:General Manager-Pharma R&D).

Symposium speaker on "Formulation and delivery of peptide/protein drugs" at the 45th Indian Pharmaceutical Congress, Indian Institute of Technology, New Delhi, India, December 24, 1993 (Host: Scientific Services Committee).

Product Development of Peptide/Protein drugs, Pharma Development, R&D, Hoechst World Headquarters, Frankfurt, Germany, December 13, 1993 (Host: Head of Pharma Galenik).

Transdermal iontophoretic delivery of peptide/protein drugs, Institut fur Pharmazeutische Technologie, der Johann Wolfgang Goethe-Universitat, Frankfurt, Germany, December 13, 1993 (Host: Dr. J. Kreuter, Professor and Department Head).

Drug delivery systems for macromolecules, conference on "Improving the drug development process", Princeton, NJ, Sept.15-16, 1992 (Host: Institute for International Research, Pharmaceutical Division).

TEACHING ACTIVITIES

Courses Taught/Mercer University
Professional/Undergraduate Level: Pharmaceutics 326 (every Spring since 1999)
Graduate Level: Team taught Biotechnology 807 (every alternate Spring since 1999) and Drug Delivery Systems 839 (every alternate Summer since 1999). Also, coordinated Graduate Seminar 897 (1999-2000).

Courses Taught/Auburn University
Professional/Undergraduate Level: *Pharmaceutical Biotechnology*: Course-Coordinator for this new course, offered first time in Fall 1998. Coordinated and taught one-third of the course; *Pharmaceutics II* (PY 302): Taught Spring 1992, 1993, 1994, 1995 and 1996; Winter 1998; covers physical pharmacy, disperse systems, parenterals, admixtures, transdermal, and aerosols; *Pharmaceutics IV* (PY 403): Introduced new topics (see new courses developed) in this course, which constitute one-fourth of the course; taught Spring 1993, 1994, 1995, 1996 and 1997; *Pharmaceutics IV Laboratory*: Introduced a laboratory on intravenous admixtures; taught Spring 1994, 1995 and 1996; *Bionucleonics* (PY537): Contribute laboratory to this course showing application of radioisotopes to drug delivery experiments; taught in Summer of 1994, 1995, 1996, 1997 and 1998.

Graduate Level: Appointed to Graduate Faculty, 6/94; Product Development (PY 603): Fall 1992; 1994; 1996 One third of a team taught course; parenterals (including laboratory); Formulation & Delivery of Peptide/Protein Drugs (PY 606): Fall 1993; Fall 1995; Winter 1997; Fall 1998.

New Courses Developed: *Formulation & Delivery of Peptide/Protein Drugs* - developed as a new 5 hour elective graduate course, which has also been approved as an elective for the inter-departmental minor in Biochemistry/Cell & Molecular Biology; Introduced two new topics to Pharmaceutics IV - "*Intravenous Admixtures*", and "*Fundamentals of Biotechnology and Pharmaceutics of Biotechnology-derived Peptide/Protein Drugs*"; Introduced a new laboratory session on "*Intravenous Admixtures*" in Pharmaceutics IV laboratory.

Researchers

Dr. Chandrasekhar Kolli, Post doctoral scholar, 2004 - Present.

Dr. Zhaowei "Bruce" Jin, Post doctoral scholar, 2004.

Dr. Nikolay A. Patrushev, Post doctoral research associate, 2001-02.

Dr. Ye Yang, Post doctoral research scholar, 2004 - Present.

Dr. Paulos G. Yohannes, Sabbatical Researcher, 2002-03.
(Professor of Chemistry, Georgia Perimeter College)

Graduate students

Major advisor/Current Ph.D. Students

Parvin Akther
Aniket Badkar
Nishil Desai
Purna Kasha
Sahitya Katikaneni
Sameer Late
Guohua Li
Jyotsna Paturi
Pravada Pendse
Srujana Siddoju
Viswatej Vemulapalli

Students Graduated

Rashmi Upasani, Ph.D., Fall 2005 (Dissertation Title: Response surface modeling to evaluate active energy assisted skin transport technologies).

Ayyappa Chaturvedula, Ph.D., Spring 2005 (Dissertation Title: Pharmacokinetic evaluation of skin transport technologies).

Dipty Joshi, Ph.D., Summer 2004 (Dissertation Title: *Transdermal delivery of recombinant human insulin via micropores*)

Advait Badkar, Ph.D., Summer 2002 (Dissertation Title: *Transdermal delivery of interferon alpha 2b*)

Rajkumar V. Conjeevaram, Ph.D., Summer 2002 (Dissertation Title: *Electrically modulated transdermal delivery of beta blockers*)

Shu-Lun Chang (Cynthia), Ph.D., Spring 2000 (Dissertation Title: *Stability study of salmon calcitonin formulation and electrically assisted transdermal delivery of calcium regulating hormones and prostaglandin E1)*

Advait Badkar, M.S., Summer 1998 (Thesis Title: *Electrically enhanced transdermal delivery of a macromolecule*)

Shu-Lun Chang (Cynthia), M.S., Summer 1996 (Thesis Title: *Enhancement of percutaneous absorption of hydrocortisone*)

Manohar Katakam, Ph.D., Spring 1996 (Dissertation Title: *Use of Non-ionic Surfactants to Stabilize Recombinant Human Growth Hormone and to Develop its Sustained Release Formulation)*

Ruchira Mitra, M.S., Spring 1994 (Thesis Title: *Investigation of factors affecting transdermal iontophoretic delivery using model compounds*)

Manohar Katakam, M.S., Fall 1993 (Thesis Title: *Aggregation of protein drugs and its prevention by carbohydrate excipient*)

Co-Major Advisor
Raj Kumar Conjeevaram, M.S., Fall 1998 (Thesis Title: *Electrically-assisted in vitro delivery of propranolol HCl through human skin*)

Sagarika Bose, M.S., Summer 1998 (Thesis Title: *Electrically-assisted transdermal delivery of buprenorphine*)

Narendra Vutla, M.S., Fall 1996 (Thesis Title: *Liposomal formulation and transdermal iontophoretic delivery of the opioid peptide leucine enkephalin*)

Committee Member

Wijaya Martanto, Ph.D., Fall 2005 (Dissertation Title: Microinjection into skin using microneedles) (External member; Wijaya was student at Georgia Institute of Technology).

Dinesh Haswani, Ph.D., Fall 2005 (Dissertation Title: Evaluation of microencapsulated gentamicin on *E.Coli* in Gram negative sepsis).

Henry Nettey, Ph.D., Fall 2004 (Dissertation Title: The evaluation of vancomycin microspheres in *S.aureus* induced sepsis).

Mary Sou, Ph.D., Spring 2004 (Dissertation Title: The effect of chitosans and other excipients on the permeation of ketotifen and other drug models through Caco-2 cells).

Zhaowei Jin, Ph.D., Spring 2004 (Dissertation Title: Microsphere formulation strategies, cell uptake studies, and pharmacokinetics in rats)

Deepali A. Damle, Ph.D., Fall 2003 (Dissertation Title: *Oral proliposomal delivery of cromolyn sodium and tiludronate: Formulation and in vitro characterization in caco-2 cells and isolated rat gut*)

Arun K. Katragadda, Ph.D., Fall 2003 (Dissertation Title: *Effect of poly(acrylate) polymers and chitosan-inhibitor conjugates on the enzymatic degradation of a model peptide desmopressin and enhancement of its transport across caco-2 monolayers and rat intestinal segments*)

Rakesh Nagilla, Ph.D., Fall 2003 (Dissertation Title: Stereospecific pharmacokinetics of ketorolac in large animal species: Evaluation of an implantable delivery system in dogs)

Michael D. Green, Ph.D., Spring 2003 (Dissertation Title: *Preparation, characterization, and in vivo evaluation of albumin-encapsulated primaquine diphosphate*)

Robert H. Marion, Ph.D., Spring 2003 (Dissertation Title: *Determination of the applicability and validity of non-isothermal kinetic methods for use in pharmaceutical stability tests*)

Wenkai Tong, Ph.D., Summer 2001 (Dissertation Title: *Evaluation of camptothecin microspheres in cancer therapy*)

Tonia R. Burk*, Ph.D., Spring 2001 (Dissertation Title: *Surface characterization and interactions in a dry powder inhalant drug delivery system*) [* external member, Tonia was a graduate student in the Department of Chemical Engineering, Auburn University, Auburn, AL].

Rajesh Kumar, Ph.D., Fall 1999 (Dissertation Title: Thermodynamic study of antibiotics and development of novel delivery systems for poorly water soluble drug)

Lin Zhang, M.S., Spring 1999 (Thesis Title: *A sustained release gel of Ceftiofur: Formulation development and in vitro characterization*)

Ram Kasina*, Ph.D., 1998 (Dissertation Title: *Preformulation and formulation studies for transdermal delivery of benazepril*) [* external member; Ram was graduate student at Mercer University School of Pharmacy, Atlanta, GA].

Deepali Damle, M.S., Summer 1998 (Thesis Title: Oral controlled release bioadhesive formulation of didanosine)

Arun Kumar, M.S., Summer 1998 (Thesis Title: Liposomal encapsulation, characterization, ocular delivery and cellular uptake of stavudine)

Shirishkumar B. Kulkarni, Ph.D., Spring 1997 (Dissertation Title: *Liposomal formulation, in-vitro characterization, delivery and cellular studies of colchicine*)

Joel S. Owen, Ph.D., Fall 1996 (Dissertation Title: "*Applications of population pharmacokinetic analysis*")

Satish Dipali, Ph.D., Fall 1996 (Dissertation Title: *In vitro and in vivo evaluation of long circulating liposomes encapsulating 2',3'-dideoxyinosine*)

Bhas Dani, M.S., Summer 1996 (Thesis Title: *Metabolism of [Des-Gly^{10}, D-Trp^{6}] LHRH ethylamide in rabbit nasal tissue: A comparison with cornea and conjunctiva*)

Evelyn Jane Ellis-Grosse, Ph.D., Spring 1996 (Dissertation Title: *The pharmacokinetics and pharmacodynamics of selected antiarrythmic agents*)

Nima Akhavein, Ph.D. in progress
Dilip Devineni, Ph.D. in progress
Alphia Jones, Ph.D. in progress
Yin Lai, Ph.D. in progress
Naveen Bejugam, Ph.D. in progress
Aladin A. Siddig, Ph.D. in progress
Nasir Uddin, Ph.D. in progress
George Yeboah, Ph.D. in progress

STUDENT RESEARCHERS

Adina Hirsch, AFPE Fellow, 2003-04
Valerie Michaud, Summer 2001, Mercer University, funded by Solvay Pharmaceuticals, GA.

SERVICE ACTIVITIES

National/State Committees

Faculty Advisor, Mercer University student chapter of American Association of Pharmaceutical Scientists (AAPS), 2003- present; *Chair*, Short Course Committee, Biotechnology Section, AAPS, 1999; Program Committee, Biotechnology Section, AAPS, 1999 and 1996; *Chair*, Education Committee,

Biotechnology Section, AAPS, 1996 and 1997; Membership Committee, Pharmaceutics and Drug Delivery Section, AAPS, 1993-1995, and was *chair* of this committee for 1994 and 1995; Publicity Liaison Subcommittee, PDD Section, AAPS, 1995; Scholarship Committee, Alabama Academy of Science, Inc., 1993-95; Newsletter Committee, Alabama Academy of Science, Inc., 1993-96.

University Committees

Mercer University: Graduate Counci, 2004 - Present.
Institutional Animal Care & Use Committee, 1999 - 2004.
Institutional Radiation Safety Committee, 2002 - 03.
Research Policies and Procedures Task Force, 2003

Auburn University: Graduate Council, 1998-99; Biogrants Committee, 1996-98; Membership Committee, 1995-96, Sigma Xi, The Scientific Research Society, Auburn University Chapter 106, Auburn Univeristy; Appointed (7/93) as participating *faculty* on the university wide inter-departmental minor in Biochemistry/Cell & Molecular Biology; Appointed (10/94) on the Steering Committee of the inter-departmental minor in Biochemistry/Cell & Molecular Biology.

School Committees/Other Service Activity

Mercer University, Atlanta, GA

Search Committee for Director, Center for Clinical Research	2004-2005
Chair, Pharmaceutics Search Committee	2003-2004
Chair, Research Award Recipient Selection Ad hoc Committee	2002-2004
Curriculum Committee	2003-2004
Resources & Facilities Subcommittee, Graduate Program Self Study	2002-2003
Chair, Distinguished Research Award Criteria Ad hoc committee	2001-2002
Web Page Sub-Committee, Centennial Celebrations	2000-2003
Publicity Sub-Committee, Centennial Celebrations	2000-2003
Assessment Self-Study Committee	2000-2002
Institutional Assessment Committee	2000-2003
Academic Performance and Standards Committee	1999-2002
Non-Academic Disciplinary Committee	1999-2000
Chair, Non-Academic Disciplinary Committee	2002-2004
Admissions Interview Team	1999-2000
Distinguished Educator Award Committee	1999-2000

Auburn University, Auburn AL

Admissions and Academic Standards Committee 1996-1998; Medical Resources Committee 1996-1998; Building Renovation Committee 1998; *Chair*, Computing Services Committee1993-1996; Computing Services Committee 1992-1996; Mentor to Students Team for Pharmacy Practice Experiences 1997-1999.

Department Committees, Auburn University

Search Committee, Pharmaceutics 1998; Chair, Ad-hoc Committee to formulate course 1996 content for new Pharmaceutical Biotechnology course 1996; B.S. in Pharmaceutical Sciences1991-92

Continuing Education

Continuing Education Presentation/Program
Parenteral Certification Program, School of Pharmacy, Auburn University, February 25, 1996, April 21, 1996, February 23, 1997, August 15, 1997, March 15, 1998, March 19, 2000, May 18, 2003, May 15, 2004, and May 14, 2005 - 5.0 hour (each time) Certification program with hands-on laboratory required by State Board for pharmacists working with parenterals; Delivery systems for biotechnology drugs, Fall 1993 C.E. Program at School of Pharmacy, Auburn University; Transdermal Drug Delivery, Fall 1992 C.E. Program at School of Pharmacy, Auburn University.

Continuing Education Articles
Articles in *US Pharmacist, Pharmacy Times, and J. Practical Nursing*; see publications list.

Peer Review Activities

Invited Book Reviews:

Reviewed a book chapter for an upcoming ACS Symposium Series Book, Polymeric drug delivery: Science and applications, October 2004.

Reviewed a book proposal for Kluwer Academic Publishers, New York, 7/02 and for CRC Press, 8/02 & 1/04.

Pharmaceutical Biotechnology: Fundamentals and essentials, Eds Melvin E. Klegerman and Michael J. Groves, Interpharm Press,Inc., 1992, for *BioPharm*, Vol.6, No.8, October 1993, p.57.

Pharmaceutical Dosage Forms and Drug Delivery Systems, Howard C. Ansel, Nicholas G. Popovich and Loyd V. Allen, Williams & Wilkins, 1995, reviewed for publisher to prepare next edition.

Pharmaceutical Dosage Forms and Drug Delivery Systems, Howard C. Ansel, Nicholas G. Popovich and Loyd V. Allen, Lippincott Williams & Wilkins, 1999, reviewed for publisher to prepare next edition.

Reviewed a book proposal for Taylor & Francis Ltd., London, UK, 10/98.

Journal Reviewer:

American Journal of Drug Delivery
Archives of Physical Medicine and Rehabilitation
Bioelectrochemistry and Bioenergetics
BIODRUGS
Critical Reviews in Therapeutic Drug Carrier Systems
Drug Development and Industrial Pharmacy
European Journal of Pharmaceutical Sciences
Experimental Biology and Medicine
International Journal of Cancer
International Journal of Pharmaceutics
International Journal of Pharmaceutical Compounding
Investigative Opthalmology and Visual Science
Journal of Controlled Release
Journal of Drug Targeting
Journal of Nanoscience & Nanotechnology
Journal of Pharmaceutical Sciences
Journal of Pharmaceutical and Biomedical analysis
Journal of Pharmacy and Pharmacology
Journal of Pharmacy Teaching
Pharmaceutical Development & Technology
Pharmaceutical Research
PharmSci, a journal of American Association of Pharmaceutical Scientists
PharmSciTech, a journal of American Association of Pharmaceutical Scientists
Physiotherapy Research International
Research Communications in Chemical Pathology & Pharmacology
Vaccine

Abstract Screening:
Joint PDD-BIOTEC Session, AAPS, 1996
Pharmaceutics and Drug Delivery Section (PDD), AAPS, 1995
BIOTEC Section, AAPS, 1998
Pharmaceutics Section, AACP, 1999
Dermal Absorption/Transport/Topical Areas, AAPS, 1999

Grant Reviews
Reviewed NIH grant proposals for Florida A&M University for their Minority Biomedical Research Support Program, April 2000 and March 2004.

Reviewer for the Mercer-Solvay Summer Research Program Grants, March 2000 and April 2002.

Member of the 1998-99 Pharmaceutics Review Panel for New Investigators Program for Pharmacy Faculty, American Association of Colleges of Pharmacy (AACP).

Other: External reviewer for Promotion & Tenure Committees at St.John's University (2004 and 2001), Western University (2002), and Campbell University (2003). Served as

a judge for the May, 1992 Graduate Research Forum for Scientific Presentations in the Sciences Category, Auburn University, AL.

PROFESSIONAL AFFILIATION

American Association of Pharmaceutical Scientists; American Association of Colleges of Pharmacy; Controlled Release Society, Inc.; Society of Cosmetic Chemists; Rho Chi; Kappa Psi; Sigma Xi

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